

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, : Civil No.
 : 07-cv-3770-DMC
Plaintiff, :
 : TRANSCRIPT OF
v. : TRIAL PROCEEDINGS
 :
ACTIVIS ELIZABETH LLC, : VOLUME 2
GLENMARK PHARMACEUTICALS INC., USA, :
SUN PHARMACEUTICAL INDUSTRIES LIMITED, :
SANDOZ INC., MYLAN PHARMACEUTICALS INC., :
APOTEX INC., AUROBINDO PHARMA LTD., :
TEVA PHARMACEUTICALS USA, INC., :
SYNTHON LABORATORIES, INC., :
ZYDUS PHARMACEUTICALS, USA, INC., :
 :
Defendants.

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Newark, New Jersey
May 19, 2010

BEFORE:

THE HON. DENNIS M. CAVANAUGH, U.S.D.J.

Reported by
CHARLES P. McGUIRE, C.S.R.
Official Court Reporter

Pursuant to Section 753, Title 28, United States
Code, the following transcript is certified to be
an accurate record as taken stenographically in
the above entitled proceedings.

s/CHARLES P. McGUIRE, C.S.R.

CHARLES P. McGUIRE, C.S.R.

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25

1 THE COURT CLERK: All rise.

2 THE COURT: Be seated.

3 Good morning.

4 Everybody here, bright-eyed and bushy-tailed?

5 All right. We have our witness, Dr. Berridge, on
6 the stand still. We were just concluding or getting close
7 to cross-examination.

8 Mr. Lipsey?

9 MR. LIPSEY: Thank you, Your Honor. I will try to
10 remain true to my word. I have just a few items.

11 C R A I G B E R R I D G E, called as a witness on behalf
12 of the Defendants, and having been previously sworn,
13 testified as follows:

14 CROSS-EXAMINATION (CONTINUED)

15 BY MR. LIPSEY:

16 Q. Dr. Berridge, when we broke, we had been debating the
17 importance of knowing the neural methods by which drugs
18 worked or the neural methods -- neural phenomenon that are
19 being affected in the brain in terms of drug design. You
20 remember that discussion?

21 A. Yes, sir.

22 Q. And I just wanted to confirm that you are the current
23 recipient of an NIH grant in the amount of about \$460,000
24 for the current year in order to do studies into the neural
25 mechanisms that underlie the cognition-enhancing actions of

1 psychostimulants and the neural biology of higher cognitive
2 function in order to provide information necessary for the
3 development of new pharmacological treatments. Isn't that
4 right?

5 A. Yes, sir.

6 Q. And as a housekeeping matter, we mentioned yesterday
7 the Riddle 1991 article, which you had considered in
8 preparing your opinions.

9 I would like --

10 MR. LIPSEY: If I may approach, Your Honor.

11 Q. -- to show you what has been marked as Plaintiff's
12 Exhibit 636, which is the Riddle 1991 article.

13 And for the record, that is the Riddle 1991
14 article you considered in forming your opinions; correct?

15 A. I think it is.

16 Q. Okay, and in the abstract, it indicates that the
17 labeling for desipramine relating to the sudden-death issue
18 had been changed in 1990; correct?

19 A. Yes, sir.

20 Q. Now, if you have the volumes that you had yesterday,
21 in Volume 3 at what's tabbed eight, there's a big fat
22 document, which is the file history of the patent-in-suit,
23 Plaintiff's Exhibit 2. Do you have that?

24 A. I have it, yes.

25 Q. Okay. And you did consider the file history of the

1 patent-in-suit in forming your opinions; correct?

2 A. Yes, sir, I did.

3 Q. And you saw very deep in the document towards the end
4 of Examiner's Reasons For Allowance that are in there;
5 right?

6 A. I'm sorry, I couldn't really hear that. What was
7 that?

8 Q. One of the things you considered was the Examiner's
9 Reasons For Allowance that appear towards the back of this
10 large file; correct?

11 A. Yes.

12 Q. Now, in that same volume at tab seven is the actual
13 patent-in-suit, Plaintiff's Trial Exhibit 1, and looking at
14 the first page of it, you see the list of some of the
15 references that are cited in that prosecution history;
16 right?

17 A. I do.

18 Q. And among them, over there on our right-hand side is
19 the Physicians' Desk Reference record for desipramine for
20 1993; right?

21 A. Yes.

22 Q. And as a matter of housekeeping, I would like to show
23 you Plaintiff's Trial Exhibit 1296, which is a copy of the
24 desipramine Physicians' Desk Reference for 1993, in fact, a
25 copy right out of the file history, and that was among the

1 things that you considered in forming your opinions;
2 correct?

3 A. It was.

4 Q. And if we look at the desipramine label in 1993, over
5 on the right-hand column under "Warnings," and go down to
6 number four, we see "Use In Children":
7 "Norpramine-desipramine hydrochloride) is not recommended
8 for use in children since safety and effectiveness in the
9 pediatric age group have not been established. (See Adverse
10 Reactions, Cardiovascular." Do you see where I've read?

11 A. Correct.

12 Q. And that was one of the things you considered in
13 forming your opinion; correct?

14 A. It is, yes.

15 MR. LIPSEY: Your Honor, I would at this point
16 like to offer into evidence for the record the prior art,
17 which was the -- in the contents of the binder we spent most
18 of the time yesterday with.

19 THE COURT: This is binder number 3? Is that the
20 one? Yes.

21 Five? Oh, five. Five.

22 MR. LIPSEY: I think it's four, Your Honor.

23 THE COURT: No, no. Five.

24 MR. LIPSEY: It's five.

25 THE COURT: Five, you said?

1 MR. LIPSEY: Five, I'm told.

2 THE COURT: Any objection?

3 MR. ROCKEY: No objection, Your Honor.

4 THE COURT: Just so we're clear, these are tabs 11
5 through 31.

6 MR. LIPSEY: Yes. For the record, I was just
7 going to read off the exhibit numbers, if I could.

8 THE COURT: Okay. Go ahead.

9 MR. LIPSEY: That included Plaintiff's Trial
10 Exhibits 5, 6, 621 and 635, and Defendants' Trial Exhibits
11 18, 20, 32, 33, 55, 59, 61, 66, 67, 93, 112, and 314.

12 And from this morning, I would offer in evidence
13 the file history, Plaintiff's Trial Exhibit 2, the
14 desipramine Physicians' Desk Reference entry, Plaintiff's
15 Exhibit 1296, and the Riddle '91 article, Plaintiff's
16 Exhibit 636.

17 MR. ROCKEY: No objection, Your Honor.

18 THE COURT: In evidence.

19 (Plaintiff's Trial Exhibits 2, 5, 6, 621, 635, 636 and
20 1296 and Defendants' Trial Exhibits 18, 20, 32, 55, 59, 61,
21 66, 67, 93, 112 and 314 marked in evidence)

22 MR. LIPSEY: Thank you very much for your time,
23 Dr. Berridge.

24 I have no further questions at this time.

25 THE COURT: Any other questions of Dr. Berridge?

1 MR. ROCKEY: We have just a few, Your Honor.

2 THE COURT: All right. Well, that's redirect.

3 Anybody else have questions before we get to
4 redirect?

5 MR. PARKER: No, Your Honor.

6 THE COURT: Okay. Redirect.

7 MR. ROCKEY: Thank you, Your Honor.

8 REDIRECT EXAMINATION

9 BY MR. ROCKEY:

10 Q. Dr. Berridge, I'd like to put up on the screen your
11 testimony from yesterday at page 220 because I had a
12 question about it.

13 Now, I'd like you to take a look at that question
14 and answer.

15 THE COURT: Just so we're clear, this is his
16 direct, or cross?

17 MR. ROCKEY: No, this is his cross, Your Honor.

18 THE COURT: Go ahead.

19 Q. And my question to you is, what were you saying there?

20 THE COURT: Well, wait. Wait a minute. I don't
21 know if it's appropriate that we're going to allow him to
22 start looking at his transcript from the day before's
23 testimony and to start explaining what he said in that
24 testimony. The testimony is what it is. If you believe
25 that something has to be clarified or you believe something

1 is unclear or you want to expand upon something, certainly
2 that's okay; but I'm not going to start going through all
3 his testimony and having him reiterate and/or clarify.

4 MR. ROCKEY: No, Your Honor, that's -- let me
5 rephrase the question. I think I can take care of it.

6 MR. LIPSEY: May we take the transcript down off
7 the screen at that point?

8 THE COURT: Well, it's not confidential. But yes,
9 we -- you can do what you want with that. Go ahead.

10 MR. ROCKEY: Thank you.

11 BY MR. ROCKEY:

12 Q. Do you distinguish, Dr. Berridge, between
13 pharmacological action and the biology of ADHD?

14 A. Yes, I do.

15 Q. And what is the distinction that you draw in that
16 respect?

17 A. Well, the pharmacological action is what the drug does
18 in a -- well, in a pharmacological sense, which is a
19 circular answer, I guess, but it's, what is the drug doing
20 immediately, what is it interacting with, physically
21 interacting with, and how does that physical interaction
22 change some process.

23 So when we talk about a reuptake blocker, it
24 blocks -- it binds the reuptake sites and it blocks those
25 actions, the actions of those reuptake sites. That's

1 something that can be measured, and that's typically how
2 drugs are described. They're described by their primary
3 action, pharmacological action.

4 When we talk about the neurobiology of ADHD, you
5 know, there, you're talking about, well, what's different in
6 the brain of ADHD subjects? And that's something we don't
7 know today, it's a complicated question, it's a difficult
8 question to answer, but that's not unique to ADHD, that's
9 common to all behavioral disorders that are treated
10 pharmacologically.

11 Q. Thank you.

12 Now I'd like to turn to the Shenker article, which
13 counsel showed you yesterday. That's PTX-6F, 1023 in the
14 big notebooks.

15 A. Are we talking about Volume 3?

16 Q. Yes. I'm sorry. Volume 5.

17 A. I'm sorry. Three was in front of me.

18 THE COURT: And which tab is this?

19 MR. ROCKEY: This is tab 23, Your Honor.

20 THE COURT: Twenty-three.

21 Q. And I'd like to have you turn to page 340 of the
22 Shenker paper.

23 A. Okay.

24 Q. Now, there's a reference there to the reduced efficacy
25 of DMI and imipramine.

1 What is that difference in efficacy referred to
2 there?

3 A. The tricyclics, including imipramine and desipramine,
4 when you compare the magnitude or the strength of their
5 efficacy in treating ADHD, although they're effective in
6 improving the symptoms, the magnitude of that effectiveness
7 is smaller than the psychostimulants.

8 THE COURT: Wait. Say that again. Smaller than?

9 THE WITNESS: Is smaller than the
10 psychostimulants. Psychostimulants give you a larger, more
11 robust therapeutic effect. The tricyclics give you a
12 therapeutic effect, but when you compare the effect size,
13 they're a little bit smaller.

14 Q. And what's the reason for that difference in effect?

15 A. No one knows.

16 Q. In terms of pharmacologically.

17 A. Well, what Shenker is pointing to, and I think this is
18 the right interpretation, is that because stimulants -- the
19 tricyclics don't have a large effect on dopamine reuptake
20 blockade, but because the stimulants do -- well, so the
21 tricyclics and the stimulants both block norepinephrine. In
22 the case of desipramine, we know that's only norepinephrine.
23 And what's different between desipramine and the
24 psychostimulants is that the psychostimulants also block
25 dopamine reuptake, increasing the levels of dopamine.

1 So if you ask the question, well, we know
2 psychostimulants are more effective than tricyclics, and we
3 know that psychostimulants do one other pharmacological
4 action than the tricyclics, that's blocking dopamine, then
5 what you say is that the better effects of psychostimulants
6 probably involve the actions of dopamine in addition to the
7 actions of norepinephrine.

8 Q. And what was Shenker's conclusion on that point?

9 A. I think that's what he concludes. Let me read this
10 paragraph.

11 Yes. So that's exactly what he's saying. The
12 reduced efficacy of imipramine and desipramine compared to
13 the stimulants is of interest because antidepressants are
14 less potent or much less potent at inhibiting dopamine
15 uptake.

16 Q. Now, that last sentence there, desipramine may be the
17 drug of choice; how do you interpret that?

18 A. Well, what they're talking about here are children
19 with chronic tic disorders, and chronic tic disorders
20 involve a malfunction of a brain region that is modulated by
21 dopamine. And dopamine -- drugs that increase dopamine
22 action tend to make the tic -- my understanding is tend to
23 make the tic symptoms or the -- exacerbates the tic
24 disorder. So you don't want to give children or anyone with
25 a tic disorder a drug that increases dopamine is my

1 understanding.

2 Q. Okay.

3 Now I'd like to turn to page 341 of the Shenker
4 paper. If you could take a look at that paragraph, what
5 does that paragraph suggest to you?

6 A. Well, I think what they're saying is that just --
7 well, what they're saying is two antidepressant -- classes
8 of drugs that are known antidepressants, the tricyclics and
9 the monoamine oxidase inhibitors, are effective in treating
10 depression and they've been used extensively for that, and
11 in general, these drugs are effective in treating ADHD,
12 there are plenty of studies that show that, but it shows
13 that not every single drug in this antidepressant category
14 will -- will necessarily be effective in treating ADHD, and
15 they point out that mianserin is an atypical antidepressant
16 and it is not effective in treating ADHD. They go on to
17 point out, as I did yesterday, that the difference here is
18 that mianserin also blocks alpha-2 receptors, and as I
19 reviewed yesterday, because alpha -- drugs that stimulate
20 alpha-2 receptors are effective in treating ADHD, it would
21 make sense that if you block those receptors, you might
22 reduce the effectiveness of a drug for treating ADHD.

23 Q. Now, yesterday, you were shown a table on page 341 --
24 a table on page 359, sorry.

25 Now, this was a prognostication, was it not?

1 A. Can you explain what you mean by that term in this
2 context?

3 Q. Let me try again with the question.

4 This was a suggestion for future work; right?

5 A. This was a suggestion for future work for drugs that
6 might match the efficacy level of the psychostimulants,
7 which again are known to be more effective in general than
8 the tricyclic antidepressants.

9 Q. And there are no -- in what Dr. -- or what this
10 publication is teaching, Dr. Shenker, is, it doesn't in that
11 table describe norepinephrine reuptake inhibitors, does it?

12 A. No.

13 MR. LIPSEY: May I?

14 As long as it will be a goosy-gander rule and that
15 leading is not going to be objectionable, it is an efficient
16 way to get it in. I just don't want to not object and then
17 be struck down.

18 THE COURT: I don't strike down anyone.

19 (Laughter)

20 THE COURT: Leading, with experts, I give a lot of
21 latitude because we can save a lot of time.

22 MR. LIPSEY: I understand.

23 THE COURT: If you think it's being overdone, if
24 either side thinks it's being overdone, but I'll allow this.
25 You'll be allowed the same latitude.

1 MR. LIPSEY: That's fine. Okay. Thank you.

2 MR. ROCKEY: Did we get a response to that?

3 THE WITNESS: Yes. Can you repeat the question?

4 MR. ROCKEY: Yes. Will you read it back, please?

5 (Record read)

6 A. No, right. So then my reply then is no, it does not,
7 again, because this is his suggestion of drugs that might
8 match the efficacy of psychostimulants, and we already knew
9 that norepinephrine reuptake blockers alone, that that's
10 what they did, did not match the efficacy of stimulants.

11 Q. Did Dr. Shenker rule out compounds which inhibit
12 reuptake of norepinephrine altogether?

13 A. In this case?

14 Q. In this paper.

15 A. No.

16 Q. Okay. Turn to page 340, and under the heading
17 "Tricyclic Antidepressants," does he have anything to say
18 about the use of norepinephrine reuptake inhibitors?

19 A. This is the same paragraph we looked at earlier?

20 THE COURT: Yes.

21 Q. Well, look at the top paragraph under this --

22 A. Okay.

23 Q. -- the top paragraph under the "Tricyclic
24 Antidepressants."

25 A. Yes. Well, this is again repeating what I've said,

1 which is that tricyclic antidepressants, and he includes
2 desipramine in that list, are indirect activators of brain
3 catecholamine receptors because they block reuptake, and
4 they're less effective in treating -- than stimulants when
5 you're treating ADHD.

6 Q. Okay. And let's go on now to Table 2 on page 342.

7 Now, this refers to drugs that have actually been
8 studied, does it not?

9 A. This refers to drugs that have been shown -- studied
10 in the context of treating ADHD and have been shown to --
11 yes, in the context of treating ADHD.

12 Q. And does this say anything about their relative
13 activity?

14 A. Well, again, this is showing that amphetamine
15 methylphenidate and pemoline are psychostimulants, they're
16 just different types of psychostimulants, and we know
17 they're very active. This monoamine oxidase inhibitor
18 class, these he's describing as very effective, and then
19 less effective is the tricyclics, and for those -- for that
20 class, he specifically lists desipramine and imipramine.

21 Q. Okay.

22 A. And that, you know, is just a summary of what the
23 clinical studies have indicated.

24 Q. What does that table tell you about the efficacy of
25 desipramine?

1 A. That it's effective, but not as effective as the
2 psychostimulants.

3 Q. And what does Dr. Shenker attribute that activity to?

4 A. As you see, norepinephrine uptake inhibition.

5 Q. Thank you.

6 One last point, Dr. Berridge. We saw on page 340
7 a reference to desipramine as a drug of choice for a certain
8 circumstance. Does anyone else suggest the use of
9 desipramine in the treatment of ADHD, any other literature?

10 A. Again, as we reviewed yesterday, there are many
11 papers, many from the Harvard research group, but not
12 solely, that have shown that desipramine is effective in
13 treating ADHD, and they point out that -- we didn't talk
14 about this yesterday, but they talk -- they point out that
15 these drugs are effective in treating ADHD in children with
16 a variety of comorbid disorders and one of them is tic
17 disorders, another one would be anxiety disorders or
18 depression.

19 MR. ROCKEY: Okay. Let's go on. We've got a
20 slide here that Dr. Berridge has not seen in its present
21 form, but let's go on to that.

22 Q. Now, the literature -- does the literature teach
23 what's illustrated in this slide, namely, the TCAs's effect
24 on norepinephrine transmission?

25 A. Yes.

1 Q. Okay. Now, you mentioned yesterday in your testimony
2 that there were other drugs that had been used in the
3 literature to treat ADHD, and I believe one of those was
4 alpha-2 agonists?

5 A. Correct.

6 Q. Okay. Let's go to that.

7 How does clonidine affect norepinephrine reuptake
8 inhibition?

9 MR. LIPSEY: Objection, Your Honor. This is
10 precisely what I was concerned about when I asked at the
11 beginning of my examination, you've got 40 references in
12 your report and you talked about seven, are you done. And
13 they said they were done and they were not relying on this
14 clonidine theory.

15 MR. ROCKEY: Well, we're not relying on it, Your
16 Honor, but Mr. Lipsey brought it up yesterday in the
17 cross-examination. I think I'm entitled to explore the
18 witness' testimony with respect to clonidine.

19 MR. LIPSEY: I showed the witness five or six
20 publications that showed what the art believed was the
21 mechanism of action for clonidine to show that it actually
22 was thought to reduce norepinephrine reuptake back in the
23 relevant time frame. That's all I did.

24 MR. ROCKEY: What I'm shooting for, Your Honor, is
25 that clonidine, as the literature suggests, that affects

1 norepinephrine transmission. Now, we're not relying on it
2 because we don't need to; but it does affect norepinephrine
3 transmission, and, of course, Mr. Lipsey opened the door to
4 clonidine when he covered it on cross.

5 THE COURT: Well, merely because he mentioned the
6 word clonidine doesn't mean that everything about it might
7 be opening the door.

8 But I truthfully just don't recollect the extent
9 of the witness' testimony regarding this.

10 I'm going to allow it.

11 MR. ROCKEY: Thank you, Your Honor.

12 BY MR. ROCKEY:

13 Q. Now, another group of compounds that Mr. Lipsey asked
14 you about yesterday, Dr. Berridge, were MAOIs, monoamine
15 oxidase inhibitors.

16 What effect would they have on norepinephrine?

17 MR. ROCKEY: Actually, Your Honor, I think I
18 forgot to have Dr. Berridge explain what clonidine does.

19 THE WITNESS: Yes. You had asked me a question,
20 but -- then you guys chatted.

21 MR. ROCKEY: Yes. I got interrupted.

22 THE COURT: Go ahead.

23 Q. Go ahead.

24 A. Okay. So when we talk about clonidine, it's a little
25 more -- it's a little more complicated, because clonidine is

1 what we call an alpha-2 agonist, it stimulates those
2 receptors mimicking norepinephrine, and when those receptors
3 are on that postsynaptic neuron, these neurons are talking
4 to each other and making the brain work in the way it works.
5 When they bind to these presynaptic alpha-2 receptors, then
6 they reduce norepinephrine release, and that's a negative
7 feedback mechanism to keep things operating within some
8 optimal range. You give an alpha-2 agonist, you're going to
9 have two parallel actions. On the one hand, you are going
10 to suppress the release of norepinephrine, as was pointed
11 out yesterday in my cross, and that had always been
12 confusing. We knew psychostimulants increase
13 norepinephrine, we knew tricyclics increase norepinephrine,
14 and the monoamine oxidase inhibitors do the same. So you
15 had three classes effective in ADHD that increase
16 norepinephrine, and one that was suppressing norepinephrine.
17 But back in the mid or late 1980's, it was discovered that
18 many alpha-2 receptors sit postsynaptically. And then there
19 was work by others who showed that when you stimulate these
20 receptors postsynaptic alpha-2 receptors, you improve
21 cognitive function that's similar in nature to cognitive
22 function affected in ADHD. And that was the basis for our
23 1993 paper that was raised yesterday as well as another
24 paper in 1994 by a woman named Coull, C-o-u-l-l, suggesting
25 that stimulating these postsynaptic alpha-2 receptors can

1 improve cognitive function, and that's probably relevant to
2 their use in the treatment of ADHD. So that explanation
3 seemed to clarify what had always been confusing to the
4 literature. And this postsynaptic alpha-2 receptor, the
5 fact that it exists, the fact that it's relevant to ADHD,
6 that took a while to percolate out of the basic neuroscience
7 literature into the clinical literature.

8 Q. Okay. You also were asked yesterday by Mr. Lipsey
9 about psychostimulants. I'm sorry, we were going back to
10 MAOI.

11 Would you explain how, if at all, MAOIs affect
12 norepinephrine transmission?

13 A. They do affect norepinephrine transmission. They also
14 affect serotonin transmission and dopamine transmission.
15 And the way they do that is, after the transmitter is taken
16 back up through these reuptake sites, this enzyme, monoamine
17 oxidase, degrades some portion of what's been taken up. If
18 you block that action, as these monoamine oxidase inhibitors
19 do, you have more neurotransmitter for release, and we know
20 that that then leads to higher levels of transmitters, or
21 the theory has always been that that leads to higher levels
22 of neurotransmitters out in that synaptic area.

23 Q. Now, the last category that you were asked about were
24 psychostimulants. Do they affect norepinephrine reuptake
25 transmission?

1 A. As I've mentioned earlier, they block both dopamine
2 and norepinephrine reuptake inhibition, and that's pretty
3 much all that they do outside in this area. At high doses,
4 amphetamine also blocks monoamine oxidase, and that's where
5 some of the theories about why you need a drug to get taken
6 up and block monoamine oxidase. But methylphenidate doesn't
7 do that or Ritalin doesn't do that, so that doesn't seem to
8 be a requirement.

9 Q. If we look at all of these drugs together that have
10 had an effect on norepinephrine transmission, what do we
11 see?

12 A. Well, --

13 MR. LIPSEY: Objection, Your Honor. This is now
14 the grand hypothesis that was supported with the 40
15 references. They relied on desipramine in their
16 case-in-chief. I object.

17 THE COURT: Well, wait. Wait. Explain that
18 again.

19 MR. LIPSEY: He had a very complicated theory in
20 his report where he synthesized the entirety of the
21 literature and looked at this drug and that drug and the
22 other drug, and he had 40 references that supported it, and
23 I was surprised when I came in and all of a sudden there
24 were seven references and all they were relying on was
25 desipramine. That was the testimony. And so I asked, is

1 that it? And I was told yes. And now on redirect
2 examination, now, the grand 40-reference theory is being
3 brought into evidence, relying now on some kind of
4 suggestion from four categories of drugs. And I think
5 that's unfair, and I object.

6 MR. ROCKEY: Your Honor, the purpose of this all
7 is to simply show that all roads lead to norepinephrine.
8 The Plaintiff has suggested that this norepinephrine theory
9 really has no foundation, and our point is simply to suggest
10 that when you consider all of the literature and all the
11 ADHD treatments that counsel brought up in cross-examination
12 yesterday, they have one thing in common: They all affect
13 norepinephrine transmission. And that demonstrates the
14 importance of norepinephrine transmission and rebuts the
15 attempt by Lilly to suggest that nobody pays any attention
16 to norepinephrine transmission any more. That's the point.
17 We're not relying on these other references. We're still
18 hanging our hat on desipramine, and we've not changed
19 theories at all. What we're doing is responding to the
20 arguments Lilly has made.

21 THE COURT: Do you agree with counsel's statement
22 that he just made that all of these things are considered?

23 THE WITNESS: All of these things are considered
24 in -- relation to something specific?

25 THE COURT: Well, as he just stated.

1 THE WITNESS: I -- I agree. I could -- I would
2 make a first point.

3 THE COURT: What's that?

4 THE WITNESS: The first point is that you don't
5 need all treatments, known treatments to work through a
6 common mechanism. We know that's true for lots of
7 disorders. You can treat it with different types of
8 treatments. Hypertension can be treated by beta agonists,
9 alpha-1 antagonists, calcium channel blockers. It doesn't
10 puzzle us that different modes of treatment would commonly
11 affect some disregulated system. So I don't think you need
12 to have all treatments have the same action, and drug
13 discovery programs have never relied on that. Depression is
14 treated by norepinephrine and serotonin reuptake blockers.
15 It's also treated by serotonin reuptake blockers. And we've
16 always used the previous drugs as the model, and from that
17 perspective, desipramine is a good model. But if you want
18 to say all these treatments don't have -- if you want to say
19 do these treatments have something in common, they do, and
20 the one thing is they increase norepinephrine
21 neurotransmission. I'm not sure that's -- you know,
22 relevant to the argument that desipramine's a good model.

23 THE COURT: Anything further?

24 MR. ROCKEY: No, Your Honor.

25 THE COURT: Any other questions on other subjects?

1 MR. ROCKEY: No, Your Honor.

2 THE COURT: Any recross?

3 MR. LIPSEY: I do have just a couple of points, if
4 I may.

5 If we could have that demonstrative exhibit that
6 was up on the board back.

7 THE COURT: Which one?

8 MR. LIPSEY: The last one.

9 MR. ROCKEY: The last one?

10 MR. LIPSEY: The last one.

11 MR. ROCKEY: You want all four?

12 MR. LIPSEY: All four.

13 RECROSS EXAMINATION

14 BY MR. LIPSEY:

15 Q. Without waiving my objection, your counsel has drawn
16 your attention to the actions of desipramine, clonidine,
17 MAOIs, and psychostimulants; correct?

18 A. Correct.

19 Q. And pharmacologically, every one of those molecules
20 does something more than simply block norepinephrine
21 reuptake; correct?

22 A. Absolutely.

23 Q. Okay. And referring to this question of postsynaptic
24 alpha-2 receptors, the clonidine work in context of ADHD
25 with postsynaptic receptors in mind really didn't hit the

1 literature until starting around 1995-'96; correct?

2 A. The first clinical studies talking about that were in
3 1995-1996. There was this 1994 paper by Coull that raised
4 this idea. We refer to it in our 1993 paper. There was a
5 neuroscience abstract, which is a publication, that was in
6 1994, I believe, with a specific mention of the use of
7 postsynaptic alpha-2 agonists in treating ADHD. That was by
8 authors that eventually went on to publish that first 1996
9 study with the postsynaptic preferring alpha-2 agonists.

10 Q. Do you have your deposition there, which I believe was
11 in volume 2, starting at page 79, line 24.

12 A. I have to find the volume.

13 THE COURT: Page 79?

14 MR. LIPSEY: I'm sorry. Page 79, line 19. It
15 will extend over onto 80.

16 Q. You were asked the following question --

17 THE COURT: Wait just one second.

18 Do you have it in front of you?

19 THE WITNESS: Line 19. Yes.

20 Q. You were asked the following question and gave the
21 following answer:

22 "QUESTION: Well, you say you don't recall, but it
23 certainly would have stuck in your mind if you had come
24 across an article which said precisely your observation,
25 right, Doctor? Wouldn't that have jumped out at you?

1 "ANSWER: Well, what jumped out at me was that
2 there were a number of papers that are talking about
3 norepinephrine. As we talked about, the clonidine work in
4 the context of ADHD, with postsynaptic receptors in mind,
5 really didn't hit the literature until starting right around
6 1995, 1996."

7 A. Correct.

8 Q. "Like I said, Amy -- " -- referring to Dr. Amy Arnsten
9 (ph) -- " -- has a published an tract in '94. She has a
10 review article along those lines in '96, which I know was
11 submit earlier than '96, but, you know, it was just getting
12 into the literature about that time. So it's not surprising
13 to me that maybe postsynaptic alpha-2 receptors weren't part
14 of the discussion."

15 That was testimony at that time; correct?

16 A. Yes.

17 MR. ROCKEY: Objection, Your Honor.

18 THE COURT: What's the objection?

19 MR. ROCKEY: Improper impeachment.

20 THE COURT: Why is that?

21 MR. ROCKEY: Because this statement is not
22 inconsistent with what he said.

23 THE COURT: Well, that's always an issue with
24 respect to impeachment.

25 It certainly clarifies, so I'm going to allow it.

1 I think it's a little bit different -- not different so
2 much, but I think it supports the position of the question.
3 So I'll allow that.

4 Go ahead.

5 MR. ROCKEY: Thank you, Your Honor.

6 BY MR. LIPSEY:

7 Q. Now, if we could go back to the Shenker article,
8 please, which is tab 23, Plaintiff's Trial Exhibit 6, and
9 it's on page 342, if we could have Table 2, to which you
10 were directed.

11 Now, you made reference to the column on the
12 right-hand side in which desipramine and imipramine were
13 described as norepinephrine uptake inhibitors; right?

14 A. Correct.

15 Q. And the heading in that column is "Proposed Major
16 Mechanism of Action"; correct?

17 A. Correct.

18 Q. So even in 1992, when Dr. Shenker is writing this
19 article, that is deemed to be the proposed major mechanism
20 of action; correct?

21 A. Consistent with the articles we reviewed yesterday
22 which cite that as the primary mechanism, correct.

23 Q. "Proposed Major Mechanism of Action," correct? That's
24 what it said.

25 A. That's what this title said.

1 Q. And if you turn to page 355 of Shenker, Plaintiff's
2 Trial Exhibit 6, under the heading "Interaction of
3 Dopaminergic and Adrenergic Systems," if we could have the
4 first paragraph, Dr. Shenker wrote there: "For the purposes
5 of clarity, the effects of drugs on brain receptors for
6 dopamine, norepinephrine and epinephrine have been discussed
7 in separate sections - this is a gross oversimplification as
8 far as their effects on the operation of the brain are
9 concerned. As mentioned, a drug is classified according to
10 the site for which it has highest affinity, but, depending
11 on dose, it may be able to interact with receptors or uptake
12 sites for several different neurotransmitters. Furthermore,
13 even highly selective agonist and antagonists can elicit
14 effects on other neurotransmitter systems because of
15 functional interconnections."

16 Do you see where I've read?

17 A. Yes.

18 Q. And you agree with that; correct?

19 A. There are two issues being raised.

20 Q. Do you agree with the statement that Dr. Shenker made?

21 A. Yes.

22 MR. LIPSEY: Thank you. We have no further
23 questions.

24 THE COURT: Anything further?

25 MR. ROCKEY: No, Your Honor.

1 THE COURT: All right. Doctor, thank you very
2 much.

3 THE WITNESS: Thank you.

4 THE COURT: You may step down, sir.

5 MR. ROCKEY: I wonder if Dr. Berridge would
6 explain something that he was -- on that last quotation from
7 Dr. Shenker's paper. I'd like to give him that explanation,
8 Your Honor -- or give him the opportunity to offer that
9 explanation.

10 THE COURT: Was there something unclear or was
11 there something further necessary to your answer to Mr.
12 Lipsey that you didn't get a chance to say?

13 THE WITNESS: I think that there was something
14 relevant to make a point, yes.

15 THE COURT: And what is that?

16 THE WITNESS: There really were two statements.
17 The first one was, we classify a drug by its primary
18 pharmacological action, but that drug could have multiple
19 actions, and we've already agreed that tricyclics do that,
20 they block the reuptake is considered the primary action,
21 the receptor actions are linked to other effects.

22 The second point was that even a highly selective
23 drug can then change other transmitter systems. That's that
24 circuitry issue, and I don't think it's relevant when we're
25 identifying drugs that might be -- when we do a drug

1 discovery analysis of what might be a useful compound,
2 that's -- after you do your receptor or reuptake site, how
3 does that then change to brain. And that's going to involve
4 one neuron talking to another to another to another and
5 you're changing that line of communication. And that's what
6 we never understood how these drugs work, these drugs or any
7 drug that affects behavior.

8 THE COURT: Anything further?

9 MR. ROCKEY: That's it, Your Honor.

10 MR. LIPSEY: Nothing further, Your Honor. Thank
11 you.

12 THE COURT: Thank you. You may step down.

13 (Witness excused)

14 THE COURT: Next witness.

15 MR. CLEMENT: Just one minute, Your Honor.

16 Your Honor, Defendants call Mr. John Goolkasian to
17 the stand.

18 MR. LIPSEY: Your Honor, from our side, my
19 partner, Mr. Burwell, will be responsible for the witness.

20 THE COURT: Okay.

21 Could we also, maybe, if we're not going to be
22 using those books that Dr. Berridge had, just move them
23 away? Only because there's not a lot of room up there and
24 we'll be crowding our witnesses.

25 MR. CLEMENT: And we have new books to bring up.

1 THE COURT: I figured you might.

2 THE COURT CLERK: Placing your left hand on the
3 bible, raising your right hand:

4 J O H N T. G O O L K A S I A N, called as a witness on
5 behalf of the Defendants, and having been duly sworn,
6 testified as follows:

7 THE COURT CLERK: Please be seated.

8 Please state your name, spelling it for the
9 record.

10 THE WITNESS: My name is John T. Goolkasian,
11 that's G-o-o-l-k-a-s-i-a-n.

12 THE COURT: Could I get that spelling again? Your
13 name, spelling, again?

14 THE WITNESS: G-o-o-l-k-a-s-i-a-n.

15 Your Honor, I should explain, I'm deaf in this
16 left ear, completely deaf, and hearing aids won't help. So
17 if you say something and I miss it, I'll try to get it.

18 THE COURT: Okay. Are you having any difficulty
19 -- well, let's see if you have any difficulty.

20 If you need to move -- if you want to move the
21 other podium over here closer, that's fine with me.

22 And, counsel, if someone can't hear, you may move
23 up, I mean, if you need to, if he's in your way.

24 MR. LIPSEY: I was just wondering if it's possible
25 to raise the volume on the microphone.

1 THE COURT: The only problem with that -- we can
2 try it, but as you heard before --

3 MR. LIPSEY: Oh, we got the feedback.

4 THE COURT: This is another system that we spent
5 about four or \$500,000 on --

6 (Laughter)

7 THE COURT: -- and what it does it, it rings. It
8 just all-around annoys me.

9 MR. LIPSEY: Okay. Okay. Fair enough.

10 THE COURT: But we can try it.

11 If you have any difficulty hearing, let me know,
12 sir.

13 MR. CLEMENT: Mr. Goolkasian, are you going to be
14 okay?

15 THE WITNESS: Yes.

16 MR. CLEMENT: I just have some witness binder
17 books.

18 DIRECT EXAMINATION

19 BY MR. CLEMENT:

20 Q. Mr. Goolkasian, are you currently employed?

21 A. Yes, I am. I'm a --

22 Q. What is the nature of your current employment?

23 A. I'm a self-employed attorney, working primarily as a
24 consultant and expert witness.

25 Q. In any particular areas?

1 A. Yes. I work in a lot of drug cases, work in the
2 electrical area and mechanical cases, especially medical
3 devices.

4 Q. Are you a patent attorney?

5 A. Yes, I am.

6 Q. How long have you been a practicing patent attorney?

7 A. I've been a practicing patent attorney since 1969.

8 Q. And do you have a technical background?

9 A. Yes.

10 Q. What is that technical background?

11 A. I have a degree in chemical engineering from
12 Northeastern University in 1956.

13 Q. And have you been employed at the Patent Office?

14 A. Yes, I've been at the Patent Office for 24 and a half
15 years at virtually all levels of the office, up to the Board
16 of Appeals.

17 Q. Okay. What positions did you hold at the Patent
18 Office?

19 MR. BURWELL: Your Honor, in order to expedite the
20 proceedings, we would be willing to stipulate to
21 Mr. Goolkasian's qualifications to testify as a Patent
22 Office practice expert.

23 MR. CLEMENT: We would like to offer him both as a
24 Patent Office practice expert and on duty of candor.

25 MR. BURWELL: We will stipulate to offering him as

1 an expert on the duty of candor as it applied during that
2 prosecution.

3 MR. CLEMENT: Okay. That's fine, Your Honor.

4 THE COURT: Okay.

5 MR. CLEMENT: I do just want to go over a couple
6 other qualifications, however.

7 THE COURT: All right.

8 MR. CLEMENT: I think they're pertinent.

9 BY MR. CLEMENT:

10 Q. Mr. Goolkasian, did you ever work on the Inter-Partes
11 -- let me just see if I can find it -- did you ever work as
12 a protest and Inter-Partes examiner?

13 A. Yes, I did.

14 Q. Okay. What is a Inter-Partes and protest examiner?

15 A. That was a group of examiners that was set up to
16 handle allegations of inequitable conduct before the Patent
17 and Trademark Office.

18 Q. Was it also known as the fraud squad?

19 A. Yes, it was.

20 Q. And what period of time did you work as an
21 Inter-Partes -- protest and Inter-Partes examiner?

22 A. I think sometime between -- from 1980 to about 1983.

23 Q. And during that time you were an Inter-Partes
24 examiner, did you also act as a staff for the Assistant
25 Commissioner of Patents?

1 A. Yes.

2 Q. And what were your duties in that regard?

3 A. Well, sometimes there were legal problems the
4 Assistant Commissioner would have that he didn't want the
5 Solicitor's Office to handle, and we would advise him on
6 that. At times when there were very hairy things in the
7 Patent and Trademark Office, like regarding genetic
8 engineering, whether we should even grant patents on that,
9 he formulated a committee and put me on the committee, and I
10 worked on that aspect of it.

11 Q. Did your duties involve the MPEP in any way?

12 A. Yes. We put in a section of the MPEP that had to do
13 with the inequitable conduct, and we put some guidelines in,
14 and I wrote some of the guidelines in there, along with a
15 group of other people.

16 Q. And what is the MPEP?

17 A. It's a group of -- it's a very large book. It sets
18 forth all the procedures of the Patent and Trademark Office
19 and how examiners should handle things and how attorneys
20 should handle things.

21 Q. Okay. Mr. Goolkasian, you worked for the Patent
22 Office. Is it okay if I just call it PTO at times today?
23 You'll understand what I mean?

24 A. I'm sorry? Yes. If you call it the PTO, yes.

25 Q. I understand that you have a slide presentation

1 prepared for your examination today.

2 A. Yes.

3 Q. Okay. Do you have a slide on the functions of the
4 PTO?

5 A. Yes.

6 The function of the PTO is really to examine
7 patent applications to determine whether or not they meet
8 the statutory requirement.

9 Q. Okay. And who participates in the patent examination
10 process?

11 A. It's an examiner, and the attorneys are agents for the
12 appellant, and it's an ex parte process.

13 Q. Okay. Does the Patent Office have goals that it
14 strives to meet?

15 A. I think there are two central goals the Office tries
16 to meet.

17 Q. Okay. Do you have a slide on that?

18 And what are those goals?

19 A. The first goal is to grant valid patents as quickly as
20 possible after filing, and the second goal is consistency in
21 patentability decisions.

22 Q. What does the Patent Office do to meet its goals of
23 granting patents as quickly as possible?

24 A. Well, the first thing they do is, they try to get the
25 examiners to examine as rapidly as possible, but you can

1 only push people so far; otherwise, the quality drops off.
2 So the next thing they do is to try to shift the work off to
3 the practitioners who are dealing with the Patent and
4 Trademark Office, and the rules regarding the duty of
5 disclosure work very well on that basis because they give
6 the examiners a lot of prior art that they wouldn't
7 ordinarily be able to get through their search systems, and
8 you get prior art from other countries who are working on
9 the same patent or counterpart patent applications, and it
10 all filters in to the Office, so you get -- you expand your
11 research facility, the assumption being that if the examiner
12 has the reference, he'll make the correct decision.

13 Q. Who gives this art, the prior art to the examiners?

14 A. Generally speaking, the attorneys and the agents who
15 are practicing before the Office. They do this in the form
16 of an information disclosure statement, and they get this
17 prior art sometimes from their own searching, from the
18 inventors, or from foreign patent offices.

19 Q. Now, the second goal you have up there is
20 "Consistency." What is consistency?

21 A. Well, this is kind of important, because you want
22 every applicant treated in the same way. You want every
23 decision to be as close to the other decision -- next
24 decision as it can be. You think of it. If you have 2,000
25 examiners in a Patent and Trademark Office, each examiner is

1 going to have his own little idea of what obviousness is and
2 what patentability is. You don't want that. You want
3 everybody to have the same idea of what obviousness is and
4 what patentability is.

5 Q. Okay. Let's talk about consistency a little more. I
6 think you have a slide on that.

7 Can you tell us how the PTO maintains consistency
8 in its patent examination?

9 A. All right. It has a section of rules, a set of rules,
10 37 C.F.R., and they've been codified, and everybody operates
11 by those rules. There are -- you can ask, petition the
12 Commissioner to waive the rules in exceptional
13 circumstances, and that will happen, but only in exceptional
14 circumstances.

15 Next is, we have a Manual of Patent Examining
16 Procedure, and the manual sets forth all the procedures for
17 -- essentially for practicing under the rules, and everybody
18 is supposed to know what's in the manual.

19 Then you have examiner training. Examiners are
20 trained, both legally, through a Patent Academy that they
21 have, or they are trained by hiring technical people to come
22 in and sometimes teach them the technology. For example,
23 when biochemistry and genetic engineering first came in, we
24 had numerous people came in to teach the examiners genetic
25 engineering, basic genetic engineering.

1 Q. Mr. Goolkasian, did you ever teach at the Patent
2 Academy?

3 A. Yes. I taught several times. I taught the basic
4 course a few times. I taught the section on 35 U.S.C. 112,
5 enablement. And I taught -- I was once chief instructor of
6 the Academy.

7 Q. Okay. Please continue.

8 A. Next you have supervisory examiners, and these are
9 picked from amongst the better examiners, and they work
10 closely with the directors and with the examiners, and they
11 supervise the work done. They train the young people, teach
12 them about patentability, teach them how to examine, and
13 they make sure that the older people who have full signatory
14 authority and are primary examiners are doing their work
15 properly.

16 Q. Mr. Goolkasian, were you ever a supervisory examiner?

17 A. Yes, I was a supervisory examiner on two separate
18 occasions.

19 Q. And how are supervisory examiners kept updated?

20 A. I'm sorry, I didn't hear that.

21 Q. How are supervisory examiners kept updated?

22 A. The supervisory examiners, indeed the whole examining
23 corps gets the USPQs, they are sent down all the time, and
24 they read them and they discuss them so they know what the
25 Court decisions are.

1 Also, the supervisory examiners talk to the
2 directors, and the directors are looking always at what
3 comes down from the Board of Appeals. And so they're having
4 legal meetings as to what the position of the Office is on
5 various issues, and they send -- they transmit this down to
6 the examiners at their meetings.

7 Q. Okay. You mentioned the USPQ. What is the USPQ?

8 A. It's a compilation of cases, like the U.S. Code or --
9 not the U.S. Code, but it's like any of the Federal Digest
10 Reporters or something like that.

11 Q. All right. Next up, you have "Quality Review." What
12 do you mean by quality review?

13 A. The quality review for -- for patent applications that
14 have been allowed, they do a random sampling of the patent
15 applications, and first our group checks to see whether
16 everything has been done properly according to the rules and
17 according to the manual, according to the procedures. And
18 then on a few cases, even lesser sampling, they look at the
19 actual decisions being made to see whether or not those
20 decisions are appropriate. And then sometimes they'll even
21 research the case to see whether the examiner found
22 appropriate prior art.

23 Q. Okay. Next up there is "Board of Appeals." How does
24 that help maintain consistency?

25 A. The Board of Appeals tries to write each of its

1 opinions to teach the examining corps what the law is as
2 they see it from what the Federal Circuit says, because the
3 Federal Circuit determines what the Board of Appeals can do.
4 And even if you disagree with the Federal Circuit, you have
5 to follow it. So that happens sometimes.

6 And they try to write the decisions to train the
7 examiners, so they try -- have consistency in decisions.

8 Q. Did you ever serve on the Board of Appeals?

9 A. Yes, I spent 10 years on the Board of Appeals.

10 Q. About how many cases did you preside over?

11 A. Well, I think in the 10 years, I can say I -- with a
12 certainty I wrote at least a thousand, maybe 1,200 opinions,
13 and I probably sat on about 3,000 cases.

14 Q. Okay. You mentioned the MPEP. Do you have a slide
15 regarding the MPEP and consistency?

16 A. Yes.

17 Here, this is a section of the MPEP, it's section
18 700, and it refers to patentability or examination, how
19 examiners are expected to examine.

20 Section 706 specifically says: "The standards of
21 patentability applied in the examination of claims must be
22 the same throughout the Office."

23 That means chemical cases are treated the same as
24 mechanical cases, the same as electrical cases; that is, the
25 law applies, the same law applies to all of them.

1 Q. Okay. Is there anything else in the MPEP that relates
2 to the PTO examination?

3 A. Yes. There's a section that applies to the Board.
4 The Board is very interested in whether or not it -- it
5 knows about other decisions that the Board makes.

6 Q. And what section do you have?

7 MR. BURWELL: Your Honor, I'm going to object.
8 There was no discussion in Mr. Goolkasian's expert report
9 about appeal briefs and requirements of appeal briefs, and I
10 would object that we did not receive fair notice that this
11 was going to be the subject of his testimony.

12 THE COURT: Is this something that -- I mean, this
13 is technical in nature. It's the manner in which we go
14 through the PTO. Is it something that -- I find that this
15 is something that you could have had notice of or be aware
16 of as a result of the fact you knew he was coming in to
17 testify on inequitable conduct.

18 No, I'll overrule the objection.

19 Go ahead.

20 MR. CLEMENT: Thank you, Your Honor.

21 Q. So is there some other section, Mr. Goolkasian, that
22 relates -- of the MPEP that relates to PTO examination and
23 consistency?

24 A. Yes. This is the section regarding preparation of an
25 appeal brief, and it says that the Board wants to know

1 related appeals and interferences, and they want a statement
2 identifying by number and filing date all other appeals or
3 interferences known to the appellant, et cetera, which will
4 directly affect or be directly affected by, and here is the
5 one that I think is important: "...or have a bearing on the
6 Board's decision in the pending appeal." If the Board
7 decides A is unpatentable in one case, and another case
8 comes up having to do with B, you have almost the same fact
9 situation, then the Board wants to decide that B is also
10 unpatentable.

11 Q. Okay. And what section of the MPEP is this?

12 A. Pardon?

13 Q. For the record, what section of the MPEP is this?

14 A. That's section 1206.

15 Q. (c) (2) ?

16 A. Yes.

17 Q. And this was -- this section was in effect in July of
18 1996?

19 A. Yes.

20 Q. Is it still in effect?

21 A. Yes, it still is in effect.

22 Q. Okay. What happens if there are inconsistent
23 decisions of the Board on similar facts?

24 A. Well, two things -- three things could happen. Number
25 one, if we allow a case one time and then we reverse the --

1 we reverse the examiner one time and that means the case
2 gets allowed, or we affirm the examiner a second time on a
3 similar fact situation, quite often, the corporations will
4 tell us that, hey, look, you guys are making the wrong
5 decision. That could happen. The directors very often will
6 tell us that, look, you guys are not being straight with us,
7 you come up with different decisions in similar cases, and
8 the Solicitor's Office could also tell us that. They could
9 be brought in.

10 What happens in that situation is, we formed a
11 five-man panel, and that five-man panel would decide the
12 case, and once that case was decided, then that would have
13 to be followed, their decision would have to be followed by
14 the entire Board.

15 Q. And did you ever serve on one of those five-man
16 panels?

17 A. Yes, fairly often.

18 Q. What are the -- what are the -- what standards govern
19 the -- or what governs the standards applied by the Patent
20 Office in making its patentability determinations?

21 A. The Patent Office uses the Graham v. John Deere
22 standards, and they've set forth guidelines as to
23 patentability.

24 Q. And have there been any recent changes to the
25 standards applied by the Patent Office?

1 A. Yes.

2 MR. BURWELL: Your Honor, I object. This
3 testimony is going into the current state of the law,
4 apparently, and does not appear relevant to the standards
5 that were applied during the prosecution of the
6 patent-in-suit. We understood he would be testifying about
7 the prosecution of the patent, and the current state of the
8 law as to obviousness would not be relevant.

9 MR. CLEMENT: Well, I think it's going to show how
10 the Patent Office applies the law to --

11 THE COURT: But he's saying it's not timely. This
12 patent was prosecuted when; '95?

13 MR. CLEMENT: '95-'96.

14 THE COURT: And now you're talking about law as of
15 today. What's the bearing on that on '95-'96?

16 I think I'm going to limit you as to what was the
17 law at the time the patent was being prosecuted.

18 MR. CLEMENT: Okay.

19 Q. Okay. I want to go back to a statement you made
20 earlier, Mr. Goolkasian, about how the applicants provide
21 information to the Patent Office. Do you recall that?

22 A. Yes.

23 Q. Okay. Does the Patent Office have rules on the duty
24 of disclosure?

25 A. Yes. They're set up in Rule 56, it sets up a duty of

1 disclosure rule.

2 Q. Okay. Do you have a slide on that, slide nine?

3 Okay. What is the duty of disclosure, duty of
4 candor?

5 A. It's a duty to provide to the examiner information
6 that would be important to the examiner in considering
7 whether or not to allow a case or to grant a patent. That's
8 what the rule is. It's Rule 56, and it supplements
9 information unavailable to the examiner through PTO
10 searches. That's one of the big -- good things about it.
11 Ordinarily, in foreign countries, they would have an
12 opposition proceeding, and that's very lengthy, and this
13 hopefully supplements all the information.

14 Q. To whom does the duty of candor apply?

15 A. It applies to the applicant, the attorney, and anyone
16 substantively involved in the prosecution of the
17 application.

18 Q. Okay. And who did it apply to with regard to the '590
19 patent?

20 A. It would have applied to the inventor -- inventors in
21 the '590 patent; it would have applied to the attorney, Mr.
22 Jones, and to Mr. Titus, an agent.

23 Q. And did you review the patent prosecution history for
24 the '590 patent?

25 A. Yes, I did.

1 Q. What is the patent prosecution history?

2 A. A patent prosecution history is a collection of all
3 the writings having to do with that patent application. It
4 includes the specification, the initial claims, and the
5 rejections, the office actions by the examiner, and
6 responses by the applicant, and any IDS's or other
7 information.

8 Q. In your opinion, what type of things should be
9 disclosed to the examiner to fulfill the duty of candor?

10 A. To be disclosed, it should disclose the closest prior
11 art, information that would be generally speaking important
12 information from foreign patent publications, and
13 information regarding adverse decisions in similar cases.

14 Q. In reviewing the '590 patent prosecution and the
15 materials related to this case, did you see anything that
16 you believed should have been disclosed to the Patent Office
17 but was not?

18 A. Yes. I saw two things. One was the Board opinion in
19 an earlier case, or a copending case, actually, but the
20 opinion was earlier, and the other was a failure to disclose
21 a tandamine reference which had been cited in a foreign
22 prosecution.

23 Q. Let's talk first about the Board opinion.

24 Who was the attorney that you believe breached the
25 duty of candor regarding the Board opinion?

1 A. That was Attorney Jones.

2 Q. Okay. And how do you know that Attorney Jones owed a
3 duty of candor with regard to the '590 patent?

4 A. Well, he filed the application. You can see his name
5 here. This is the application transmittal form, letter, and
6 he filed it, and he put his telephone number down on it.
7 When the attorney puts his telephone number down, that means
8 they should call him in case they want to allow it on the
9 first Office action, something like that.

10 Q. And this is from the patent prosecution history, DTX-2
11 at STPAT page seven?

12 A. Yes.

13 Q. Okay. Do you know of any other documents that show
14 Attorney Jones was involved in the '590 patent?

15 A. Yes. This is -- there is another -- another document
16 here. This is the Declaration and Power of Attorney, and at
17 the very bottom, in the right-hand side, it says direct
18 telephone calls to Joseph Jones and gives a telephone number
19 again.

20 Q. And this is from the prosecution history, DTX-2 at
21 STPAT page 18?

22 A. Yes.

23 Q. And what about any other documents that show that
24 Attorney Jones was involved in the '590 patent?

25 A. The next document you see would be a Response to an

1 Office Action, and this tells me that his actions weren't
2 just merely ministerial, they were actually substantive,
3 because here he is actually writing a response to the office
4 action and telling why he thinks it's patentable.

5 Q. And this again came from the file history, DTX-2 at
6 pages 33 to 37?

7 A. Yes.

8 Q. Okay. What was it that Attorney Jones failed to
9 disclose to the Patent Office?

10 A. He failed to disclose an earlier Board opinion in a
11 case having to do with the use of atomoxetine for its
12 norepinephrine reuptake inhibition properties as a treatment
13 for enuresis.

14 Q. Is this an MPEP section that talks about disclosing
15 Board opinions?

16 A. Yes. This is the section on inequitable conduct, and
17 it advises that the information relating to or from
18 copending United States Patent Applications should be
19 brought to the attention of the examiner or other Office
20 official involved with the examination of a particular
21 application.

22 Q. Okay. And this came from DTX-202?

23 A. Yes.

24 Q. And that's an MPEP section that was in force in
25 January of 1995?

1 A. Yes, it was.

2 Q. Do you know why this is required?

3 A. Well, why this is required is because quite often,
4 applicants will have a group of applications in the Office
5 on similar subject matter and will get rejections by one
6 examiner and allowances or no rejections by another. And
7 they want to have consistency, so they want the examiner
8 who's not rejecting to know that it's been rejected by
9 someone else.

10 Q. Okay. And what was the prosecution history? What
11 patent was it that the Board opinion appeared in that
12 Mr. Jones did not disclose to the Patent Office?

13 A. That was a patent we could call the '985 patent.

14 Q. Is that up on the Board now?

15 A. Yes.

16 Q. And is that DTX-6?

17 A. Yes. It's a patent to Foreman, and it's number
18 5,441,985, and it's directed to "a method of treating
19 urinary incontinence comprising administering to a human
20 suffering from urinary incontinence an effective amount of
21 tomoxetine or a pharmaceutically acceptable salt thereof."

22 Q. And did you also review the prosecution history for
23 this patent?

24 A. Yes, I did.

25 Q. And is that at PTX-293?

1 A. Yes, it is.

2 Q. Okay, and was the claim that was pending at the time
3 -- is the claim that was pending at the time of the Board
4 opinion up on the screen?

5 A. Yes. That's claim 6.

6 Q. Okay. And did that differ from the claim that was
7 finally issued?

8 A. Not significantly.

9 Q. Okay. Why would a patent directed to urinary
10 incontinence be material to the '590 patent?

11 A. Because the mechanism by which it's treated is the
12 same mechanism, namely, norepinephrine reuptake inhibition,
13 and that's very important, because ordinarily you might say,
14 what does urinary incontinence have to do with ADHD? But
15 remember, it's the mechanism of operation, and that's what's
16 going to be important to the Office.

17 Q. Okay. We also have the '590 patent up there; correct?

18 A. Yes.

19 Q. Okay. Is there any comparison between those claims?

20 A. Yes. The '590 patent says "a method of treating
21 attention deficit/hyperactivity disorder comprising
22 administering to a patient in need of such treatment an
23 effective amount of tomoxetine." So aside from the fact
24 that the problem being treated is different in both cases,
25 the actual drug being administered and the administration

1 technique is the same.

2 Q. Okay. Are there any other reasons why you believe
3 this urinary incontinence material would be relevant here?

4 A. Oh, most definitely. In fact, I think Mr. Jones
5 believed it was material.

6 Q. And how do you know that?

7 MR. BURWELL: Objection, Your Honor.

8 THE COURT: I'll sustain the objection as to what
9 Mr. Jones believed.

10 MR. CLEMENT: Okay.

11 MR. BURWELL: And I'd also object to any testimony
12 concerning this Springer reference. This was not identified
13 in his expert report either as a basis for any opinion that
14 he was going to offer at trial, and we were never afforded
15 the opportunity to cross-examine him at his deposition on
16 this issue.

17 MR. CLEMENT: It's in the file wrapper. It's in
18 the patent '590 file wrapper, and I believe that
19 Mr. Goolkasian discussed the IDS in the file wrapper.

20 THE COURT: Am I correct in assuming that when he
21 listed that which he relied upon for his expert opinion, he
22 listed the PTO file wrappers?

23 MR. CLEMENT: Yes.

24 THE COURT: I'll allow it.

25 Q. Okay. Did Mr. Jones cite a urinary incontinence

1 patent to the Patent Office?

2 A. Yes, he did.

3 Q. And how do you know that?

4 A. Because when I looked at this, I saw Springer, and it
5 said urology, and I said, well, what does that have to do
6 with this subject matter? Until I looked at what it said.
7 It was "Facilitatory and Inhibitory Effects of Selective
8 Norepinephrine Reuptake Inhibitors on Hypogastric
9 Nerve-Evoked Urethral Contractions in the Cat." And this is
10 -- so this is being sent in because the attorney is sending
11 in material information to the Patent and Trademark Office.
12 So they put the urology thing in there. The only assumption
13 I could make is that at that time, it would have been
14 material. Otherwise, it's foolish to put it in.

15 Q. This information disclosure statement was found at
16 DTX-2, STPAT 29 to 30?

17 A. Yes.

18 Q. Can you explain to the Court what an information
19 disclosure statement is?

20 A. Yes. The information disclosure statement is a way
21 that applicants and their attorneys can comply with the duty
22 of disclosure. The information disclosure statement lists
23 references that they believe could be material, that a
24 reasonable examiner would want to know in examining the
25 application. And these are the references listed. For

1 example, the Springer reference is listed down at the bottom
2 there, all of those things that were talked about by
3 Mr. Lipsey this morning, physicians' Desk References, I
4 think, all of those were before the examiner, too, in this
5 IDS. So the examiner knew about those things.

6 Q. Is the information in an IDS supposed to be correct?

7 A. Pardon?

8 Q. Must the information in an IDS be correct?

9 A. Yes.

10 Q. Are patent attorneys supposed to cite nonmaterial art
11 to the Patent Examiner?

12 A. Hopefully not.

13 Q. And why not?

14 A. Because it just increases the amount of work the
15 Office has to do.

16 Q. Was there something else in the '590 patent
17 prosecution you're relying on to say the Board opinion in
18 the urinary incontinence patent was material to the '590
19 patent?

20 A. Yes.

21 Q. And what is that?

22 A. The examiner cited the Ryan reference. And when you
23 read the Ryan reference, he shows that the norepinephrine
24 reuptake inhibition --

25 MR. BURWELL: Objection, Your Honor. He's now

1 giving technical testimony, and he's not qualified as a
2 technical expert to provide such testimony.

3 MR. CLEMENT: I think he's explaining what the
4 examiner did.

5 MR. BURWELL: He's talking about what the Ryan
6 reference disclosed.

7 THE COURT: Could I have the beginning of what he
8 was saying?

9 (Record read)

10 THE COURT: Well, it sounds like he was talking
11 about what is in the Ryan reference, doesn't it?

12 MR. BURWELL: Right, and he does not have the
13 technical background to understand that.

14 THE COURT: How about it?

15 MR. CLEMENT: I can move on.

16 THE COURT: Good.

17 BY MR. CLEMENT:

18 Q. Okay. Mr. Goolkasian, did you review the '985 patent
19 file history?

20 A. Yes, I did.

21 Q. Okay. Is the '985 prosecution history relevant to the
22 '590 examiner's reasons for rejecting the application?

23 A. In my opinion, it is.

24 Q. And why is that?

25 A. Because it sets forth the rationale for the Board of

1 Appeals in this type of substitution of one chemical for
2 another.

3 Q. And was that rationale found in an Office action?

4 A. Yes, it is.

5 Q. And was that the Office action PTX-293, page 65?

6 A. This now is the examiner's rationale, but it's very
7 similar to the Board's. The examiner says that the
8 applicant had made some remarks regarding the combination of
9 references by saying they weren't structurally similar
10 chemicals, and the examiner says the "Remarks regarding the
11 structure of tricyclic drugs are not well taken since the
12 rejection is not based upon the similarity of the structures
13 of the drugs, but rather the mechanism of action and the
14 information taught regarding the norepinephrine uptake
15 inhibition."

16 Q. Okay. Did Attorney Jones ever appeal that decision?

17 A. Yes, he did.

18 Q. Okay. What we have up on the screen, is that the
19 letter transmitting a brief on appeal?

20 A. Yes.

21 Q. And that's at PTX-293 at pages 74 to 79?

22 A. That's correct.

23 Q. Okay. What is an appeal?

24 A. An appeal is a case wherein the examiner has decided
25 that a subject matter before the examiner is not patentable,

1 at least some subject matter, and the examiner has finally
2 rejected the claims, and once claims have been twice
3 rejected, the examiner can -- the applicant can appeal the
4 rejection, and the applicant decides to go to the Board to
5 see if the Board will overrule the examiner and say that it
6 is patentable, whereas the examiner has said that it was
7 unpatentable.

8 Q. Okay. And what was the claim that Mr. Jones appealed?
9 Is that up here on the Board?

10 A. Yes. That's the same claim 6 we saw before.

11 Q. Okay.

12 A. "A method of treating incontinence, et cetera,
13 comprising administering to a human suffering from
14 incontinence, et cetera, an effective amount of tomoxetine
15 or a pharmaceutically acceptable salt thereof."

16 Q. Okay. And we already discussed how that compared to
17 claim 1, so we'll move on from that.

18 Did this appeal proceed to a Board opinion?

19 A. Yes, it did.

20 Q. Okay. Do you have a slide on that Board opinion?

21 A. Yes.

22 Q. And what did the Board say?

23 A. The Board was going -- I first started talking about
24 the argument that was made, the rationale that was made by
25 the appellant in that case. They say: "We do not consider

1 the rationale to be well taken. One having ordinary skill
2 in the art would have been taught by the applied references
3 that tomoxetine was known in the prior art to inhibit
4 norepinephrine uptake (again see, for example -- " -- they
5 used the Zerbe reference in that -- " -- and that the
6 inhibition of norepinephrine uptake was known in the prior
7 art to control incontinence," et cetera. And they cited
8 Cohen for that.

9 "Further, norepinephrine uptake inhibition is only
10 one factor which would have been considered in selecting a
11 compound for use in treating the disorders in question.
12 Other factors such as side effects would have been
13 considered, and Zerbe's teaching that tomoxetine produces
14 relatively mild side effects would have militated for use of
15 this compound for treating these disorders."

16 Q. Okay.

17 A. In other words, the Board is saying because they have
18 the same mechanism of action, it's obvious to substitute one
19 chemical that works by the same way for another chemical
20 that works by the same way. And then they said also, look,
21 if you have lesser side effects, that's good, that's one
22 reason to use it.

23 Q. Okay. And this is the Board opinion at DTX-210, and
24 the pages that you're reading from are from pages 87 to
25 89 --

1 A. Yes.

2 Q. -- for PTX-293?

3 And why are these statements material to the '590
4 patent in your opinion?

5 A. Well, because the examiner had made a very similar
6 rejection in his case dealing with ADHD, and had the
7 examiner known that the Board would have affirmed that
8 rejection, the examiner would never have allowed those
9 claims.

10 Q. Okay. Have you prepared a slide with the side-by-side
11 comparison?

12 A. Yes. The Board's opinion in the '985 patent
13 application is on the left-hand side, and the examiner's
14 opinion is on the right-hand side in the '590. And you can
15 see both sides, "tomoxetine was known in the prior art to
16 inhibit norepinephrine uptake. And "the inhibition of
17 norepinephrine uptake -- " -- and the examiner just simply
18 called that monoamine uptake -- " -- was known in the prior
19 art to" in one case control incontinence, in the other case
20 to treat ADHD.

21 And then he said: "Other factors such as side
22 effects would have been considered, and Zerbe's teachings
23 that tomoxetine produces relatively mild side effects would
24 have militated for use of this compound...."

25 Ryan said "tomoxetine was known to have

1 'potentially fewer side effects.'"

2 Q. Do you have another slide to show how the rationale
3 from the Board opinion in '590 were analogous?

4 A. Yes, I do. This takes the Board opinion, just
5 substitutes -- it's going to substitute the examiner's
6 reasoning and references.

7 MR. BURWELL: Your Honor, I object to this slide
8 and the one before it and the whole substitution that just
9 happened. After this substitution, the language in the
10 upper portion of this slide does not accurately reflect the
11 rejection that was made by the examiner during the '590
12 patent prosecution.

13 MR. CLEMENT: I think it accurately reflects that.
14 It's my understanding it completely accurately reflects it.

15 MR. BURWELL: The slide he just talked about said
16 that the examiner's rejection of the '590 patent application
17 talked about the inhibition of monoamine uptake, and he's
18 now changed the words "monoamine uptake" to "norepinephrine
19 uptake was known in the prior art."

20 That's completely inaccurate.

21 MR. CLEMENT: Norepinephrine is a monoamine. I
22 don't see where it's changed much. I think Mr. Goolkasian
23 is just showing how the decisions were analogous.

24 THE COURT: I'm going to allow it.

25

1 BY MR. CLEMENT:

2 Q. So, Mr. Goolkasian, how did this slide show that one
3 rationale from the Board opinion was analogous to the '590?

4 A. Yes, it does. It also shows what the law was back at
5 that time, because -- what the Board would have factored
6 according to the law.

7 Q. Is it your opinion, Mr. Goolkasian, that the Board
8 decision was material to the '590 patent application?

9 A. In my opinion, it most definitely was material to the
10 '590 application.

11 Q. Now, you were present at Dr. Berridge's testimony
12 yesterday?

13 A. Yes, I was.

14 Q. And you heard his testimony on urinary incontinence?

15 A. Yes.

16 Q. Does that change your opinion as to the relevance of
17 the Board opinion?

18 A. No, not at all. I think it's very unfair to ask
19 technical witnesses information about patent law, and he's a
20 technical expert. And in the Patent Office, we get
21 questions of analogous side, one analogous side all the
22 time. And the Patent Office is considering here the
23 mechanism of the way the drug works, and that's what's
24 important, not the fact that the disease or two somewhat
25 dissimilar diseases, you might say. But that's essentially

1 it. The Office is concerned with the way the drug works.

2 Q. Okay. I'm sorry. I guess I didn't identify for the
3 record this Board opinion one that we were looking at:
4 PTX-293 at 87 and 89.

5 All right.

6 MR. BURWELL: I'm sorry, I have to object. This
7 statement that is now on this slide is not present in --

8 THE COURT: This is the transfer of --

9 MR. BURWELL: This is after his substitution, and
10 this statement on the slide does not appear in any trial
11 exhibit.

12 THE COURT: Isn't that so?

13 MR. CLEMENT: That's true, yes.

14 Why don't we flip back to before we changed it?

15 That slide accurately reflects PTX-293?

16 MR. BURWELL: We're okay with that slide.

17 MR. CLEMENT: Thank you.

18 BY MR. CLEMENT:

19 Q. All right. Now, Mr. Goolkasian, did you find any
20 evidence from which one might be able to infer that
21 Mr. Jones had an intent to conceal the Board opinion from
22 the examiner?

23 MR. BURWELL: Again, objection as to testimony
24 regarding intent.

25 THE COURT: I'll sustain that.

1 MR. CLEMENT: Okay. I don't think I'm asking
2 about Mr. Jones's state of mind, just circumstantial
3 evidence from which intent could be inferred.

4 THE COURT: I don't know how I divide that up.
5 I'll sustain that objection.

6 Q. Mr. Goolkasian, what happened after the Board's
7 opinion?

8 A. After the Board's opinion, he refiled the case.
9 Actually, he refiled the case before the Board's opinion but
10 forgot to tell the Board, and so the Board went through its
11 process of deciding the case. And then he saw the opinion
12 came out, and he tried to get it withdrawn, he tried to get
13 it -- the Board to take away its opinion, and he says, "The
14 undersigned realizes -- " -- he wrote a letter to request
15 the Board to withdraw the appeal, and in that request, he
16 said: "The undersigned realizes the significance of his
17 oversight and assures the Board that the error will not be
18 repeated..."

19 Q. This is from PTX-293 at pages 105 to 106?

20 A. Yes.

21 Q. Have you ever come across one of these withdrawal
22 requests during your 25 years at the Patent Office?

23 A. Well, such withdrawal requests are very rare. They're
24 not usually made because they're -- when you refiled the
25 case, they're going to be in the file anyway and the

1 examiner's going to know what the Board's opinion was. So
2 they're not usually done.

3 THE COURT: So what's the reason for filing the
4 withdrawal?

5 THE WITNESS: I -- honestly, Your Honor, I can't
6 figure why he asked for that.

7 THE COURT: All right. Go ahead.

8 Q. What did the Patent Office do with Mr. Jones's request
9 to withdraw?

10 A. It denied it.

11 Q. And we have that --

12 A. This is a letter from Fred McKelvey, the Chief Judge.

13 Q. And this is at PTX-293 at pages 114 and 115?

14 A. Yes.

15 Q. Mr. Goolkasian, is it your opinion that Attorney Jones
16 breached his duty of candor with regard to failing to
17 disclose the Board opinion?

18 A. Well, if you look at it, he -- he knew of the Board
19 opinion, he knew of its significance, and he didn't submit
20 it.

21 MR. BURWELL: I'll object to his testimony
22 concerning knowledge of the significance of the Board's
23 opinion.

24 And while the slide is up, I'll object to any
25 testimony concerning evidence of intent.

1 THE COURT: Yes, I don't know how he can testify
2 as to what he knew.

3 Why don't you go back to that question and answer,
4 the question that's asked, the original question that you
5 asked?

6 MR. CLEMENT: Okay. Could you repeat the question
7 for me? Thank you.

8 (Record read)

9 A. Yes.

10 Q. Did Mr. Jones know about the Board opinion?

11 A. Yes.

12 Q. Did he prosecute the '590 application?

13 A. Yes, he did.

14 Q. And what was the -- did you find a comparison between
15 the two?

16 A. Yes, the fact situation -- from the Board's viewpoint,
17 this -- from the Board's viewpoint, the legal situation was
18 exactly the same.

19 Q. All right. Let's turn back to -- let's go to slide 27
20 regarding the instances of a breach of duty of candor that
21 you found in the second one, slide 27.

22 A. Okay.

23 Q. Okay. What was the second instance of breach of duty
24 of candor that you found?

25 A. This is a failure to disclose the tandamine reference.

1 Q. And where did the tandamine reference appear?

2 A. The tandamine reference appeared during prosecution of
3 a counterpart application in the European Patent Office, and
4 it was in a search report that was given to Lilly regarding
5 that application.

6 Q. Okay. What is a foreign counterpart?

7 A. It's an application filed in a foreign country that
8 has, generally speaking, usually the same specification and
9 claims as in the U.S. case.

10 Q. Okay. Are there any PTO guidelines regarding foreign
11 counterparts?

12 A. Yes. The PTO wants to see references that are cited
13 in that foreign case.

14 Q. And how do you know that?

15 A. This is a section of the MPEP, it's 2001.06, and it
16 says: "Applicants and other individuals, as set forth in 37
17 CFR 1.56, have a duty to bring to the attention of the
18 office any material prior art or other information cited or
19 brought to their attention in any related foreign
20 application." And it says: "The inference that such prior
21 art or other information is material is especially strong
22 where it has been used in rejecting similar claims."

23 Q. In the foreign application?

24 A. Yes.

25 Q. Which section of the MPEP did this come from?

1 A. It came from -- this, again, the duty of disclosure
2 section, it's 2001.06(a).

3 Q. Okay. And that's DTX-202?

4 A. Yes.

5 Q. Okay. Next slide, did you prepare a timeline for us
6 so we can see how the events occurred?

7 A. Yes.

8 The application was filed in January 11th, 1995,
9 this is for the '590 patent, and the European application
10 was filed a year later, on January 9th, 1996.

11 On October 8, 1996, a different individual, Mr.
12 Titus, a patent agent, he submitted a brief in the '590 --
13 appealing the '590 final rejection.

14 Q. Okay. Weren't we talking about Mr. Jones before?
15 Where did this Mr. Titus come from?

16 A. Yes. Apparently Mr. Jones was no longer on that case,
17 and the case was parsed out to Mr. Titus.

18 Q. And how do you know that Mr. Titus became involved in
19 the prosecution of the '590 patent?

20 A. Because his name appears on the brief.

21 Q. Okay. And is this the brief at DTX-2 STPAT 44-51?

22 A. Yes. And if we look, we see this docket number
23 X-9726. That's on almost all the papers in that file, and
24 it's also on papers in the European application file.

25 Q. Is that a Patent Office docket number, or is that

1 internal?

2 A. That's a training docket number.

3 Q. And this does show that Mr. Titus was responsible for
4 this brief?

5 A. Yes.

6 Q. Okay. And did you review the appeal brief?

7 A. Yes, I did.

8 Q. Did the brief argue for separate patentability of the
9 dependent claims?

10 A. No, it did not. Here we have the examiner rejected
11 the claims under 35 U.S.C. 103, he treated claims 1 through
12 16 as a unit, and the Board -- the appellant, with the
13 Board, he grouped the claims as a unit, which means that as
14 far as the Board and the examiner are concerned, claims 2
15 through 16 do not offer anything which is patent -- makes
16 claim 1 patentable.

17 Q. So the quote at DTX-2, STPAT 26, that came from the
18 examiner?

19 A. Yes.

20 Q. And the one at DTX two, STPAT 45, that came from Mr.
21 Titus?

22 A. Yes.

23 Q. What does that mean, that the claims stand or fall
24 together?

25 A. That means that the applicant is willing to accept

1 that there is nothing in the dependent claims 2 through 16
2 which makes claim 1 patentable.

3 Q. Going back to the timeline, what's the next time
4 point?

5 A. December 23rd, 1996, the examiner allowed the
6 application for the '590 patent. And then on January the
7 17th, the European Patent Office issued a search report on
8 the counterpart application.

9 Q. Okay. Let's go back to the December 23rd, 1996 date.

10 Did Mr. Titus's duty to disclose end then?

11 A. No. The duty to disclose continues until the patent
12 is granted.

13 Q. And how do you know that?

14 A. Pardon?

15 Q. And how do you know that?

16 A. Because it's in the rule.

17 Q. And your timeline also shows that the European search
18 report issued?

19 A. January 17th, 1997.

20 Q. Okay. Did you prepare a slide regarding the European
21 search report?

22 A. Yes.

23 Q. Mr. Goolkasian, what is a European search report?

24 A. In foreign countries, even in the United States now,
25 but in the foreign countries, at least back then, and even

1 then, I guess, they do a search report first. That gives
2 the patent owner the opportunity to see what prior art they
3 have found in the Office so the owner can decide whether or
4 not to continue prosecution of that application. But there
5 is no office action on it and there's no application of the
6 prior art or the claims. It's just a statement of what they
7 thought was the closest prior art.

8 Q. Okay. And this is found, this European search report
9 is found at DTX-257 at STPAT 406 to 407?

10 A. Yes.

11 Q. Okay. And are there E references listed on that
12 European search report?

13 A. Yes.

14 Q. What is an E reference?

15 A. An E reference is stated right at the bottom where it
16 says "Category of Cited Documents." It's an earlier patent
17 document, but it's published on or after the filing date, so
18 it's not really a reference.

19 Q. Okay. And what about, is there -- were there Y
20 references on that search report?

21 A. Yes. A Y reference is a reference that's considered
22 by the examiner to be particularly relevant if combined with
23 another document of the same category.

24 Q. And what is the Y reference that you have highlighted
25 there?

1 A. The Y reference is a reference having to do with
2 tandamine, a new norepinephrine reuptake inhibitor.

3 Q. Okay. Going back to the timeline, what is the next
4 point?

5 A. The next point is, Titus -- we know that Titus
6 received the search report on February the 11th, 1997.

7 Q. Well, I think we have a time point January 28.

8 A. Oh. I'm sorry. I just didn't see that.

9 January 28, Lilly in the U.K. sent the search
10 report to Titus.

11 Q. Okay, and then Mr. Titus received it when?

12 A. Yes, he received it on February the 11th, 1997.

13 Q. And how do you know this?

14 A. Because he initialed it.

15 MR. CLEMENT: Okay. Can we have that?

16 Q. Is this the document from which you know it?

17 A. Yes. He initialed it. It shows his initials. It
18 shows he got a copy of the search report, it was enclosed
19 with this cover letter, and a copy of the citations is also
20 enclosed.

21 Q. Okay. This is DTX-212?

22 A. Yes.

23 Q. And how do you know this is relating to the European
24 search report?

25 A. Because it's got this docket number. Remember this

1 X-9726? They just put an "EP" after it, which means
2 European.

3 Q. And does this say that this also enclosed a copy of
4 the citations?

5 A. Yes.

6 Q. And did this all occur before the '590 patent issued?

7 A. Yes.

8 Q. Okay. Were there any other documents showing that --
9 were there any other documents showing that '590 and the
10 European application were counterparts of each other?

11 A. Yes, there were.

12 If you look at the '590 patent, it has an
13 application serial number 371,341, filed January 11, 1995,
14 and this is the European published application. It claims
15 priority of the same serial number 371,341, which is down
16 at, marked 30, so it's the same priority application.

17 Q. Okay. And you're looking at DTX-224 at STPAT 944333?

18 A. Yes, and someone has put in hand, again, that X-9726
19 number up in the upper right-hand corner.

20 Q. Can we just go back quickly to slide 34? I think I
21 didn't say something -- or I didn't say something correctly
22 for the record.

23 Mr. Goolkasian, this European search report was
24 found at DTX-277 at STPAT 945406 to 407?

25 A. Yes.

1 Q. Thank you. Sorry.

2 Mr. Goolkasian, is it your opinion that the
3 tandamine reference is material?

4 A. Well, it's a Y reference, and Y references are usually
5 considered material.

6 Q. And you mentioned earlier that Mr. Titus was involved
7 in the '590 prosecution; correct?

8 A. Yes.

9 Q. So is it your opinion he owed a duty of candor to the
10 Patent Office with regard to the '590 patent?

11 A. Yes.

12 Q. And did the prior slides we saw show he had knowledge
13 of the European search report and the tandamine reference?

14 A. Yes.

15 Q. Did Mr. Titus ever submit the European search report
16 or the tandamine reference to the Patent Office?

17 A. No, he did not.

18 Q. Could he have?

19 A. Yes, he could have. There's a procedure where one
20 simply files a petition and pays a fee, and the Office will
21 look at it.

22 Q. Did you find evidence that he filed that procedure in
23 other cases?

24 A. Yes.

25 Q. Okay. In what other cases?

1 A. There were two other cases. One was the '070 patent,
2 and the other was the '222 patent.

3 There's a third one, too. There's a Canadian
4 counterpart application.

5 Q. Okay. Let's take a look at the '070 first. Did you
6 review the '070?

7 A. Yes, I did.

8 Q. And the prosecution?

9 A. Yes.

10 Q. And the '070 patent is up there on the screen now?

11 A. Yes, it is.

12 Q. And that's DTX-7?

13 A. Correct.

14 Q. And what is this patent about?

15 A. This is a treatment of oppositional defiant disorder
16 using tomoxetine. Atomoxetine, it has here.

17 Q. And does it have the same inventor as the '590?

18 A. Yes, it does.

19 Q. And does it list the same attorney?

20 A. Yes, it does.

21 Q. Okay. What happened in that '070 prosecution history?

22 A. In that prosecution history, a European search report
23 came in, and it was submitted to the examiner after a notice
24 of allowability.

25 Q. And the '070 prosecution history, that's PTX-301?

1 A. Yes.

2 Q. Okay. And this notice of allowance is found at
3 PTX-301 at page 69 and 70?

4 A. Yes.

5 Q. Was this a submission of a European search report
6 after the application was allowed?

7 A. Yes, it was.

8 Q. And how long after the search report was issued by the
9 European Patent Office did Mr. Titus submit it to the U. S.
10 Patent Office?

11 A. Well, he submitted it within the three-month window.
12 You have a three-month window of opportunity to send it from
13 the time the search report was issued by the foreign patent
14 office till the time you send it in to the Office.

15 Q. And how do you know that?

16 A. Well, because as a rule, it says so. It's 37 C.F.R.
17 1.97(d) and (e), and it's (e) that says about the three
18 months, I believe.

19 Q. And this rule specifically applies to counterpart
20 foreign applications; correct?

21 A. Yes.

22 Q. And this rule was in effect --

23 A. Well, it applies to any foreign application that you
24 have.

25 Q. And this was in effect in September of 1995?

1 A. Yes.

2 Q. Okay. The other patent you mentioned was the '222
3 patent?

4 A. Yes.

5 Q. And what is -- the '222 patent, that's DTX-8?

6 A. Yes. This is another invention by Dr. Heiligenstein
7 that goes to the treatment of conduct disorder using drugs,
8 one of which could be tomoxetine, and for the norepinephrine
9 inhibition uptake property, and -- it, too, had a foreign
10 counterpart.

11 Q. Okay. And did you review the '222 prosecution
12 history?

13 A. Yes.

14 Q. Okay. And what happened there?

15 A. On June 28, 1999, there was a notice of allowability.
16 On July 14th, 1999, Mr. Titus submitted the search report
17 from the European counterpart applications of the PTO.

18 Q. Okay. And the notice of allowability, that's at
19 PTX-300 at page 80?

20 A. Yes.

21 Q. And the information disclosure statement where Mr.
22 Titus submitted the search report from the counterpart
23 application to the Patent Office is at PTX-300 at page 82?

24 A. Yes.

25 Q. Okay. What happened as a result of how Mr. Titus

1 submitted the European search report during the prosecution
2 of this '222 patent application?

3 A. Well, in this one, he didn't follow that petition
4 procedure and so they didn't accept the IDS form, so what he
5 did is, he filed a continued prosecution application.
6 That's what that is, is, you simply pay a fee and then
7 you're entitled to continue the prosecution. The
8 prosecution is reopened, and you pay the fee, you continue
9 the prosecution. And then he submitted an IDS that
10 contained the references that were cited in the European
11 search report.

12 Q. Okay. And the PTO rejection of the IDS, that was at
13 PTX-300 at pages 90 to 91?

14 A. Yes.

15 Q. And then Mr. Titus's submission of the continued
16 prosecution application was at PTX-300 at page 92?

17 A. Yes.

18 THE COURT: How much longer are we going to be,
19 counsel?

20 MR. CLEMENT: Probably another 10, 15 minutes.

21 THE COURT: Is this a good time to take a short
22 morning break?

23 MR. CLEMENT: We can certainly do that.

24 THE COURT: Okay. Why don't we take about 15
25 minutes?

1 You can step down, sir.

2 (Recess taken)

3 THE COURT: Be seated.

4 (The witness resumed the stand.)

5 THE COURT: Okay?

6 MR. CLEMENT: Ready to continue. Thank you, Your
7 Honor.

8 BY MR. CLEMENT:

9 Q. Mr. Goolkasian, when we left off, I think we talked
10 about Mr. Titus requesting a continued prosecution
11 application to resubmit the IDS?

12 A. Yes.

13 Q. Okay. What happened there?

14 A. So after he -- he didn't get approval of the original
15 one, so he filed a continued prosecution application, I
16 think I testified to that, and then he submitted an
17 information disclosure statement which included in it the
18 references or some of the references that have been cited in
19 the examination report.

20 Q. The European report?

21 A. Yes.

22 Q. And he submitted this information disclosure statement
23 on September 22, 1999?

24 A. Yes.

25 Q. And this appears at PTX-300 at pages 97 to 98?

1 A. Yes.

2 Q. Let's go back to your timeline.

3 Okay. So when did Mr. Titus pay the issue fee?

4 A. I'm sorry, I didn't hear the exact question.

5 Q. I'm sorry. When does the timeline reflect that
6 Mr. Titus paid the issue fee?

7 A. Mr. Titus paid the issue fee on March the 17th, 1997.

8 THE COURT: For the record, that's St. Patrick's
9 Day.

10 (Laughter)

11 MR. CLEMENT: Thank you, Your Honor.

12 Q. And then the patent issued on August 19th, 1997.

13 A. Yes.

14 Q. Did the prosecution continue in Europe?

15 A. Yes, it continued in Europe.

16 Q. And also in Canada?

17 A. Yes.

18 Q. Okay. Was the tandamine reference cited in the
19 Canadian counterpart application?

20 A. Yes, it was.

21 Q. Okay. Do you have a slide on that?

22 A. This is the Canadian counterpart application, and we
23 know that it's claiming the same priority of the 371,341
24 application filed in the United States.

25 Q. Okay. And this is -- what Canadian Patent Application

1 Number is this?

2 A. It's 2,209,735.

3 Q. And this is found at PTX-760 at STPAT 944346?

4 A. Yes.

5 Q. And this was the counterpart to the '590 patent;
6 correct?

7 A. Yes.

8 Q. And how do you know this was the Canadian counterpart?

9 A. Because it's got this -- all this Canadian information
10 on it, and it refers back to the United States of America
11 application 371,341.

12 Q. And did you review the file wrapper history for the
13 Canadian patent '735?

14 A. Yes, I did. I had a redacted version of the file,
15 though.

16 Q. And do you recall seeing who was involved in the
17 prosecution of the Canadian application?

18 A. Yes. The Canadian application was prosecuted by a
19 Canadian law firm, but they were dealing with Mr. Titus.

20 Q. Okay. This is a letter you have up there on the
21 screen?

22 A. Yes. This is a letter from the Canadian law firm to
23 Mr. Titus, indicating "I enclose herewith, a copy of the
24 request for expedited examination, along with a copy of the
25 Preliminary Amendment as filed."

1 Q. And this has the same reference number in the Re line,
2 X-9726?

3 A. Yes.

4 Q. Okay, and do you know if a European search report was
5 submitted to the Canadian Patent Office?

6 A. Yes, I do. It was submitted to the Canadian Patent
7 Office.

8 Q. And how do you know that?

9 A. Because I've seen it, the document, in the file.

10 Q. And is where you saw it up on the screen now?

11 A. Yes, this is the preliminary amendment, and it says
12 that "Applicant encloses herewith a copy of the first page
13 of US Patent No. 5,658,592, a copy of US form PTO 1449, a
14 copy of the International Search Report and of the
15 corresponding European Search Report."

16 This is the European search report on the
17 right-hand side, and it shows this tandamine reference being
18 submitted to the Canadian Patent Office.

19 Q. Okay, and the first page of that preliminary
20 amendment, that's found in PTX-760 at STPAT 944375?

21 A. Yes.

22 Q. And the European search report is from the same
23 Exhibit at 944381?

24 A. Yes.

25 Q. Did you see Mr. Titus stating anything to the Canadian

1 Patent Office about the lack of materiality of this Y
2 reference?

3 A. No.

4 Q. Okay. Now, this document also refers to an
5 International Search Report. Do you see that?

6 A. Yes.

7 Q. Okay. Did you review that as well?

8 A. Yes, I did.

9 Q. What is a PCT search report?

10 A. Well, sometimes when -- if someone wants to file a
11 patent application in several different countries, they can
12 file one in a PCT country and designate all the rest, and
13 they get the examination in the country, and what happens
14 is, when they do that, the PCT country that's doing the
15 examination, they do what is called a search report in the
16 same way that European office would do it, and the search
17 report, in this case, the examination country was the
18 United States, and the search report was by Examiner Spear,
19 the same examiner who had examined the '590 patent in the
20 United States, and the search report lists the same
21 references, and they were all Y references, and they were
22 submitted to the Canadian Patent Office.

23 Q. When you say "same references," what do you mean?

24 A. This is the references that the examiner had used to
25 reject the claims. This PCT is dated -- has different dates

1 on it than what the examiner's actual rejection dates are.

2 Q. And you're talking about the examiner's rejection in
3 the '590 patent?

4 A. Yes. Yes. But it's the same references, they're all
5 listed as Y, and the examiner just sends -- sends them.

6 Q. Y: Was that the same category that was given the
7 tandamine reference in the European search report?

8 A. Yes, it's the same category.

9 Q. Have you read Mr. Titus's deposition transcript?

10 A. Yes, I did.

11 Q. Do you recall him saying that he considered the
12 tandamine reference but did not cite it to the Patent
13 Office?

14 A. That's correct.

15 Q. Okay. Is this the testimony you were referring to?

16 A. Yes. He says that he didn't cite it, and that he made
17 an independent determination about whether the references
18 needed to be cited in the U.S. case.

19 Q. And this is from a deposition held on September 4th,
20 2008 at page 61, lines seven to 10, line 17 -- and page 62,
21 lines two to eight?

22 A. Yes.

23 Q. Do you also recall him testifying that he did not make
24 a note to the file regarding his independent determination?

25 A. That's correct. He was specifically asked if he had

1 recorded this information anywhere, and he said --

2 THE COURT: You know, counsel, I don't know
3 whether it's appropriate that we're just having him read
4 testimony from somebody who hasn't testified here as a
5 witness.

6 Is this going to be read into evidence, or what is
7 it?

8 MR. CLEMENT: We haven't been told whether or not
9 Mr. Titus is going to come to trial.

10 THE COURT: Well, what rule allows us to just pick
11 up somebody's deposition testimony and read it when they're
12 not a party to the action?

13 MR. CLEMENT: Okay. We can take it down.

14 Q. Mr. Goolkasian, do you recall testifying as to whether
15 or not he made a note to the file regarding his independent
16 determination?

17 THE COURT: Well, that's the same question, it's
18 just that he's not reading the testimony.

19 Is there an objection to any of this?

20 MR. CLEMENT: I haven't heard one.

21 THE COURT: No, neither have I.

22 MR. BURWELL: Your Honor, I question --

23 THE COURT: Is this gentleman going to be
24 testifying? Or is his testimony going to be read into the
25 record?

1 MR. LIPSEY: If I may intercede as in loco
2 parentis --

3 (Laughter)

4 MR. LIPSEY: -- we're trying to plan out our case.
5 We have witness availability issues for witnesses who have
6 to be in the Canadian trial in the same action. And Mr.
7 Titus did testify fully in his deposition about these
8 matters. We haven't yet decided --

9 THE COURT: You have no objection to this?

10 MR. LIPSEY: The point is, if we don't bring him,
11 we are going to let the deposition come in, and for that
12 reason, I think in fairness to them we ought to allow them
13 to use the deposition.

14 THE COURT: All right. If that's the situation,
15 okay.

16 MR. CLEMENT: Thank you.

17 A. All right. Well, then, I'll read it --

18 (Laughter)

19 THE COURT: Spoken like a true lawyer.

20 (Laughter)

21 A. It says:

22 "QUESTION: And do you recall whether or not you
23 made any notes on the -- on the review of the prior art?

24 "ANSWER: I do not recall.

25 "QUESTION: When you called upon to produce

1 documents or look for documents in connection with the
2 production in this litigation?

3 "ANSWER: Yes, I was.

4 I misspoke. It says Were You Called Upon.

5 He says, "Yes, I was."

6 "QUESTION: I take it you checked to see if you
7 had any notes?

8 "ANSWER: Yes.

9 "QUESTION: And you didn't find any?

10 "ANSWER: I did not."

11 BY MR. CLEMENT:

12 Q. Okay. This was from Mr. Titus's deposition at page
13 63, lines six to 17?

14 A. Yes.

15 Q. On September 4th, 2008?

16 A. Yes.

17 Q. Okay. Is there an MPEP section that's relevant to
18 this?

19 A. Yes. This is the "Aids to Compliance With Duty of
20 Disclosure" where the MPEP and the Patent Office tried to
21 tell the bar different things they had to do to make life
22 easier for everybody on inequitable conduct issues, and the
23 very last line says: "If information was specifically
24 considered and discarded as not material, this fact might be
25 recorded in an attorney's file or applicant's file,

1 including the reason for discarding it. If judgment might
2 have been bad or something might have been overlooked
3 inadvertently, a note made at the time of evaluation might
4 be an invaluable aid in explaining that the mistake was
5 honest and excusable. Though such records are not required,
6 they could be helpful in recalling and explaining actions in
7 the event of a question of 'fraud' or 'inequitable conduct'
8 raised at a later time."

9 Q. Okay. Did Mr. Titus follow that guideline?

10 A. No, he did not.

11 Q. This guideline's found at DTX-202 at pages 2000-8?

12 A. Yes.

13 Q. And it's January 1995?

14 A. Yes.

15 MR. CLEMENT: I just want to go back quickly to
16 slide 48. It appears I forgot to identify that for the
17 record. This was Gowling's letter to Mr. Titus, Exhibit
18 PTX-770 at STPAT 944379.

19 Q. Okay. Mr. Goolkasian, when you were here yesterday,
20 did you also hear Dr. Berridge talk about tandamine?

21 A. Yes.

22 Q. And did what Dr. Berridge say change your opinion?

23 A. No, not really. The reference was a Y reference. It
24 seemed to be important enough to give to the Canadian Patent
25 Office. It talks about a new norepinephrine -- by its very

1 title a new norepinephrine reuptake inhibitor, and so it
2 could very well have been material to a reasonable examiner.
3 Anyway, I think he should have submitted it.

4 Q. So does it remain your opinion that Mr. Titus breached
5 his duty of candor by failing to submit the tandamine
6 reference?

7 A. Yes.

8 MR. CLEMENT: Okay. Your Honor, I just want to
9 move some exhibits into the record.

10 I have DTX-2, 6, 7, 8, 52, 107, 202, 205, 210,
11 211, 212, 216, 224, and I have PTX-293, 300, 301, and 760.

12 THE COURT: Any objection?

13 I assume these are all of these documents that
14 you've been using.

15 MR. CLEMENT: Yes.

16 MR. BURWELL: No objection to these documents.

17 THE COURT: Into evidence.

18 (Plaintiff's Trial Exhibits 293, 300, 301 and 760 and
19 Defendants' Trial Exhibits 2, 6, 7, 8, 52, 107, 202, 205,
20 210, 211, 212, 216 and 224 marked in evidence)

21 MR. BURWELL: We do reserve objections as to the
22 demonstratives.

23 THE COURT: Well, he didn't offer them.

24 MR. CLEMENT: I didn't offer those.

25 I just have one other housekeeping matter, I

1 guess.

2 Can we go back to the PCT search report?

3 I'm being told that this should have been PTX-760
4 at 944,377, not 366, I apologize, for the record.

5 THE COURT: Any objection to the change?

6 MR. BURWELL: No objection.

7 THE COURT: Okay.

8 MR. CLEMENT: I pass the witness.

9 THE COURT: Cross-examine.

10 MR. BURWELL: Good morning, Your Honor. Scott
11 Burwell for Plaintiff Eli Lilly and Company.

12 CROSS-EXAMINATION

13 BY MR. BURWELL:

14 Q. Good morning, Mr. Goolkasian.

15 A. Good morning.

16 Q. Are you able to hear me all right?

17 A. I'm sorry?

18 (Laughter)

19 Q. I take it the answer is no. I asked you if you were
20 able to hear me okay.

21 A. Yes, I can hear you okay.

22 Q. If you are unable to hear me, please let me know, and
23 I'll do my best to speak up.

24 A. I will.

25 Q. You've been handed a collection of binders. Among

1 them are your deposition testimony from this case, your
2 expert report, and some other materials that we may be going
3 into over the course of the cross-examination.

4 First, I'd like to talk a little bit about your
5 background.

6 Now, you testified on your direct examination that
7 you have an undergraduate degree in chemical engineering.

8 Is that correct?

9 A. Yes.

10 Q. But you don't have any advanced degrees, do you?

11 A. No, I have no advanced degrees. The only thing that I
12 did have of an advanced nature was that in 1983, after I
13 wrote Ex Parte O'Farrell, I had to really learn to
14 understand biochemistry because I was going to get a lot of
15 genetic engineering cases, so I took a year of biochemistry
16 at the National Institute of Health Graduate School.

17 Q. Okay. That was a class that you had audited?

18 A. Yes, I audited it, actually.

19 Q. You were not actually in the laboratory doing
20 experiments as part of that class, were you?

21 A. No, I didn't do any of that. I was too old.

22 Q. Now, you're not a person of ordinary skill in the art
23 as to which the '590 patent-in-suit is directed, are you?

24 A. No.

25 Q. And you've never worked for a pharmaceutical company,

1 have you?

2 A. That's correct.

3 Q. And you've got no experience in the medical field?

4 A. No.

5 Q. And you're not an expert in neurotransmitters, are
6 you?

7 A. No, I'm not.

8 Q. You've got no experience with ADHD, do you?

9 A. None.

10 Q. Now, when -- you can't place on these technical
11 references that have been discussed the nuances that a
12 technical expert could, could you?

13 A. That's correct, I couldn't do that.

14 Q. And you know nothing about ADHD other than what you've
15 read in the documents that counsel for the Defendants have
16 provided to you; is that correct?

17 A. I know nothing about ADHD other than what I've read in
18 the documents.

19 One of the previous questions you asked, I
20 couldn't put the nuance as would a technical person, but I
21 could as would a Patent Examiner, because that's what I did
22 for years.

23 Q. Now, in the course of your work on this matter, you
24 did not independently look for any other art beyond that
25 what was provided to you by Defendants' counsel, did you?

1 A. That is correct.

2 Q. And you have not reviewed in the course of your work
3 on this matter the opinions that Lilly's expert, Dr.
4 Pliszka, has rendered in this case, have you?

5 A. That is correct.

6 MR. BURWELL: Could we have DTX-2 up on the
7 screen, please?

8 Q. And that should be tab one of your binder, volume one.

9 A. Okay. I see that.

10 Q. And if I can direct your attention to the page with
11 the Bates number STPAT 23.

12 A. I am having trouble finding -- okay.

13 Q. It would be at tab one, the first document in your
14 binder.

15 A. I hear that.

16 Q. And there are numbers in the lower right-hand corner
17 of each page.

18 A. What is the Bates number?

19 THE COURT: Twenty-three. Have it?

20 THE WITNESS: No. Sorry.

21 THE COURT: Counsel, why don't you assist him?

22 THE WITNESS: Are you saying 43?

23 THE COURT CLERK: Twenty-three.

24 THE WITNESS: Twenty-three.

25 Q. Okay. Mr. Goolkasian, are you with me on page 23 now?

1 A. Yes.

2 Q. Okay. Now, this is, is it not, the information
3 disclosure statement that Mr. Jones submitted during the
4 prosecution of the '590 patent; correct?

5 A. Yes, it is.

6 Q. Okay. And you talked about citation of references to
7 the Patent Office, and you mentioned 37 C.F.R. section 1.97.
8 Do you remember that? That was in the context of submitting
9 references to the Patent Office after a notice of allowance;
10 right?

11 A. Yes.

12 Q. Now, that same section of the Code of Federal
13 Regulations, 37 C.F.R. 1.97(h), states that "The filing of
14 an information disclosure statement shall not be construed
15 to be an admission that the information cited in the
16 statement is or is considered to be material to
17 patentability as defined by section 1.56(b)."

18 You agree with that; correct?

19 A. That's correct.

20 Q. So merely because a reference is cited in an IDS is
21 not an admission that it is material information; correct?

22 A. Well, it isn't a legal admission, but the question is,
23 why would an attorney cite it unless he believed it was
24 something an examiner would want to know? Otherwise he's
25 just hiding, burying the important references in this

1 blizzard of paper.

2 MR. BURWELL: Objection, Your Honor.

3 THE WITNESS: The IDS does not say --

4 THE COURT: Wait. Wait. Hold it.

5 Let me hear the question again.

6 (Record read)

7 THE COURT: And the answer?

8 (Record read)

9 THE COURT: All right. I'll allow that.

10 The question is answered.

11 Next question.

12 Q. If you look at the first sentence in the IDS, Mr.
13 Jones says: "As a means of complying with the duty of
14 disclosure, Applicants submit a 'List of References Cited By
15 Applicant' on a modified PTO-1449 form and provide a copy of
16 each of the listed references for consideration by the
17 Examiner." Correct?

18 A. Yes.

19 Q. And if I can turn your attention to pages 29 and 30 of
20 DTX-2, --

21 A. Okay. I see that.

22 Q. -- the references that were identified by Mr. Jones
23 are listed on those pages of the form; is that correct?

24 A. Yes.

25 Q. And among those references that Mr. Jones identified

1 and submitted copies of to the Patent Office were the three
2 references that the examiner ultimately applied as the basis
3 for his rejection in the prosecution of the patent; is that
4 correct?

5 A. Yes, I believe so.

6 Q. If I can turn your attention back to page five of
7 DTX-2, and what's then blown up on the screen is a box that
8 says "Searched," with handwritten notes.

9 This indicates that the examiner made searches of
10 the Patent Office files for art during the course of his
11 examination of this application; correct?

12 A. Yes.

13 Q. And the examiner did not locate any additional
14 references beyond those that had been submitted to and by
15 Mr. Jones; correct?

16 A. I -- I didn't hear all of that question.

17 MR. BURWELL: Could you read it back, please?

18 THE COURT: Okay. But we're not going to keep
19 reading back. What you're going to have to do is keep your
20 voice up. Again, I'll say to you what I said to whomever
21 else: If it's easier for you to move your thing over,
22 you're welcome to, but otherwise, keep your voice up so the
23 gentleman can hear you.

24 MR. BURWELL: Certainly, Your Honor.

25 THE COURT: You can read that question back,

1 Chuck.

2 (Record read)

3 A. That's correct.

4 Q. Okay. Let's talk a little bit about the urinary
5 incontinence application.

6 Now, as some background, you have no familiarity
7 with urinary incontinence, do you?

8 A. That's correct.

9 Q. And you don't know what stress incontinence is?

10 A. Correct.

11 Q. And you don't know what causes stress incontinence, do
12 you?

13 A. That's right.

14 Q. Okay. Now, the '590 patent concerning the use of
15 tomoxetine to treat ADHD is not a continuation application
16 of the '985 application directed to urinary incontinence, is
17 it?

18 A. No, it's not. It has a different inventor.

19 Q. And it's not a continuation in part either?

20 A. That's correct.

21 Q. And you mentioned that the inventors are different
22 between the ADHD patent and the urinary incontinence patent;
23 correct?

24 A. Yes.

25 Q. Now, you mentioned the Board of Appeals opinion in the

1 urinary incontinence application, and if we could pull up
2 PTX-293, which should be tab five of your binder.

3 A. I have that. Which particular page is that?

4 Q. I will direct you to page 76, and focusing your --
5 I'll wait till you're with me.

6 A. I have that.

7 Q. If I can direct your attention to the last paragraph
8 on the page, this is Mr. Jones's appeal brief in the
9 prosecution of the urinary incontinence patent; correct?

10 A. Yes.

11 Q. And in this brief, he states that: "Appellant agrees
12 that the Cohen reference draws the link between
13 norepinephrine uptake inhibition and the lower urinary
14 tract. Cohen admittedly makes norepinephrine inhibitors
15 likely urinary tract disorder treatments. Therefore, the
16 examiner is correct in contending that tomoxetine was known
17 as a norepinephrine inhibitor and that norepinephrine
18 inhibitors are known to affect the lower urinary tract and
19 detrussor muscle."

20 Do you see where I've read?

21 A. Yes.

22 Q. And that's because the Cohen reference had reported
23 the effects of nisooxetine on the lower urinary tract;
24 correct?

25 A. I don't remember the exact chemical that Cohen had

1 used.

2 MR. CLEMENT: Your Honor, you know, he didn't let
3 him testify about references before. He's trying to do it
4 on cross.

5 THE COURT: Yes. I mean, I think we should keep
6 our eye on the ball here. This witness is testifying
7 regarding the inequitable conduct and the activities at the
8 PTO. We seem to be getting into these technical issues that
9 he's already acknowledged no expertise in.

10 MR. BURWELL: I'll move on, Your Honor.

11 MR. CLEMENT: Thank you, Your Honor.

12 BY MR. BURWELL:

13 Q. If I can direct your attention to page 87 of PTX-293.

14 Now, this is the opinion that was issued by the
15 Board of Appeals that you testified about on your direct
16 examination; correct?

17 A. Yes.

18 Q. Turning to the first paragraph, beginning in the
19 second sentence: "One having ordinary skill in the art
20 would have been taught by the applied references that
21 tomoxetine was known in the prior art to inhibit
22 norepinephrine uptake," citing Zerbe, "and that the
23 inhibition of norepinephrine uptake was known in the prior
24 art to control incontinence, detrusor instability or
25 interstitial cystitis (again, see, for example, Cohen)."

1 Do you see where I've read?

2 A. Yes.

3 Q. And that was the basis for the Board's opinion in the
4 prosecution of the urinary incontinence application;
5 correct?

6 A. Correct. That, plus the -- the fact that the
7 tomoxetine had less side effects. That was another
8 advantage that they would have seen.

9 Q. Now, if I can direct your attention back to the
10 prosecution history of the '590 patent, tab one, and
11 specifically, page 27.

12 A. I have that.

13 Q. Now, this is from the examiner's first rejection of
14 the claims of the '590 patent; correct?

15 A. Yes.

16 Q. And if I can direct your attention -- the examiner has
17 cited the Ryan, the Green, and the Wong references in
18 support of that rejection; correct?

19 A. Yes.

20 Q. And I'll turn your attention to the second paragraph.
21 The second sentence reads: "Both Green and Ryan suggest
22 using drugs which are selective inhibitors of monoamine
23 uptake in nerve terminals, such as, fluoxetine to treat
24 (ADHD) ."

25 Do you see where I've read?

1 A. Yes.

2 Q. And fluoxetine is not a norepinephrine uptake
3 inhibitor, is it?

4 MR. CLEMENT: Your Honor, again, I think that's
5 getting technical.

6 THE COURT: How about it?

7 THE WITNESS: Do you want the answer?

8 THE COURT: No. Hold on.

9 MR. BURWELL: I'll withdraw it.

10 THE COURT: Yes, I think what we have here is,
11 this is going to be a continuing problem. I'm not going to
12 let him get into all this technical stuff.

13 MR. BURWELL: I will stay away from the technical
14 stuff, Your Honor.

15 THE COURT: The technical chemicals.

16 BY MR. BURWELL:

17 Q. Okay. Let's go back to the prosecution history of the
18 urinary incontinence patent, PTX-293.

19 A. Which exhibit is --

20 Q. I'm sorry. That's tab five of your binder.

21 A. Tab five. And which page are we looking at?

22 Q. If I can direct your attention to page 105.

23 Now, this is a document that you've testified
24 about on your direct examination concerning Mr. Jones's
25 request to withdraw the Board opinion?

1 A. Yes.

2 Q. Now, this request was submitted in July of 1994;
3 correct?

4 A. That's correct.

5 Q. And the '590 patent application regarding the use of
6 tomoxetine for ADHD was not filed until January of 1995;
7 correct?

8 A. The -- I'm sorry, could you repeat that question? I
9 didn't -- the numbers are getting me here.

10 Q. Yes.

11 The request to withdraw the Board of Appeals
12 opinion in the urinary incontinence case was submitted in
13 July of 1994; correct?

14 A. Yes.

15 Q. And then the '590 patent application involving
16 tomoxetine for ADHD wasn't filed until January of 1995;
17 correct?

18 A. Yes.

19 Q. Which means that this request for withdrawal of the
20 Board opinion was made over five months prior to the filing
21 of the '590 patent application; isn't that right?

22 A. Yes. They were still copending, though.

23 Q. But the request to withdraw the Board opinion was made
24 before any application had even been filed in the '590
25 patent application; correct?

1 A. Yes. I don't understand the relevance. I'm sorry.

2 Q. Let me see if I can simplify it.

3 The '590 patent application had not been filed at
4 the time that this request to withdraw the Board opinion was
5 made; correct?

6 A. I understand the fact. I'm just trying to understand
7 the relevance, that's all.

8 THE COURT: Well, I'll deal with the relevance.
9 Let's --

10 THE WITNESS: I'm sorry.

11 THE COURT: Go ahead.

12 Q. And, in fact, the reason that -- well, let's walk
13 through this request to withdraw the opinion on appeal.

14 You understand from this document that Mr. Jones
15 had submitted this request because the application that was
16 the subject of the appeal to the Board had actually been
17 abandoned prior to the issuance of the Board opinion;
18 correct?

19 A. Yes.

20 Q. And that's because Mr. Jones had submitted a file
21 wrapper continuation of that application before the Board
22 actually issued its opinion; correct?

23 A. Correct.

24 Q. And that filing of the file wrapper continuation
25 occurred over a year before the Board issued its opinion;

1 correct?

2 A. I didn't check exactly the dates on that.

3 Q. So the claims that were on appeal to the -- well,
4 let's back up, and I can have you confirm for yourself.

5 If you go back a few pages to page 96, --

6 A. I have that.

7 Q. Do you understand this page to be the first page of
8 the file wrapper continuing application that Mr. Jones filed
9 on May 13th, 1993?

10 A. Yes.

11 Q. And that was over a year prior to the Board of
12 Appeals' issuance of its opinion on the appeal; is that
13 correct?

14 A. That is correct.

15 Q. If I can direct your attention to page 99, do you
16 recognize this as a preliminary amendment that Mr. Jones
17 submitted in connection with the file wrapper continuation
18 application for the urinary incontinence application?

19 A. Yes.

20 Q. And do you see where Mr. Jones canceled claims 7
21 through 10?

22 A. Yes.

23 Q. And do you understand that the claims that were the
24 subject of the appeal before the Board of Appeals included
25 claims 6 through 10? Correct?

1 A. That's correct.

2 Q. So some of the claims had no longer -- let me back up.

3 The file wrapper continuation application acts as
4 an express abandonment of the application, of the parent
5 application; correct?

6 A. It should, yes.

7 Q. So the application that was the subject of the appeal
8 to the Board had been abandoned prior to the time the Board
9 issued its opinion on the appeal; correct?

10 A. Yes.

11 Q. Okay. Can we go back to page --

12 MR. CLEMENT: I think the witness was trying to
13 explain his answer.

14 A. I'm having a little difficulty there. Usually when
15 one files a file wrapper continuation, one says, abandon the
16 previous application, and then one notifies the Board. But
17 that statement isn't in this -- this filing.

18 Now, it may operate by way of rule, and I didn't
19 check that.

20 Q. And, indeed, it does operate by way of rule, doesn't
21 it?

22 A. I'll accept your representation to that.

23 Q. And it did at the time of the filing of this
24 application. We understand that the terminology and some of
25 the rules have changed in the interim; correct?

1 A. I'll accept your representation. Correct.

2 Q. If I can turn your attention back to page 105, this is
3 Mr. Jones's request to withdraw the opinion on appeal? Is
4 that correct?

5 A. Yes.

6 Q. This is what you testified about on your direct
7 examination?

8 A. Yes.

9 Q. Now, Mr. Jones, does he not, explains the reason for
10 this request to withdraw the opinion. In the second
11 paragraph, he states: "On May 13, 1993, Appellant by his
12 undersigned attorney filed a file wrapper continuation under
13 Rule 62, requesting the express abandonment of the
14 above-titled application as part of the procedure."

15 And then he attaches Exhibit A of the filing
16 receipts and Exhibit B, the Rule 62 application form.

17 Do you see where I've read?

18 A. Yes.

19 Q. And then if you can turn to the next page, --

20 A. Yes.

21 Q. -- looking at the carryover paragraph and the next two
22 paragraphs, Mr. Jones also attaches a copy of the
23 preliminary amendment that he had submitted and says:
24 "Thus, the only claim which is common to the continuation
25 application and to the claims on appeal is claim 6."

1 "Appellant's attorney inadvertently failed to ask
2 for the withdrawal of the above-titled application from
3 appeal, upon the filing of the Rule 62 continuation.
4 Therefore, the Board's time was wasted in a needless
5 consideration of the case and preparation of the Opinion.
6 The undersigned realizes the significance of his oversight
7 and assures the Board that the error will not be
8 repeated..."

9 Do you see where I've read?

10 A. Yes.

11 Q. So Mr. Jones was apologizing for, in effect, wasting
12 the Board's time; is that correct?

13 MR. CLEMENT: Your Honor, I think that goes to
14 Mr. Jones's state of mind.

15 THE COURT: I think it does, and I think that was
16 the subject matter of objections to this --

17 MR. BURWELL: I'll move on.

18 Q. Now, as of July of 1994, apart from the application
19 that was pending concerning urinary incontinence, you
20 haven't seen any other evidence of any other applications
21 that had been filed by Lilly concerning uses of tomoxetine;
22 correct?

23 A. I haven't seen any, other than the two later
24 applications.

25 Q. And the later application was filed in January of

1 1995; correct?

2 A. Yes.

3 Q. And you haven't seen any evidence that anybody at
4 Lilly as of July of 1994 had contemplated any later
5 applications involving tomoxetine, have you?

6 A. I have no idea of -- I haven't seen any evidence, and
7 I can't read Lilly's mind.

8 Q. Now, you submitted a declaration in conjunction with
9 the briefing on a summary judgment motion in this case. Do
10 you recall that?

11 A. Yes.

12 Q. And that declaration should be in front of you in
13 another binder, Volume 4.

14 A. I have that.

15 Q. And do you recognize this as the declaration that you
16 submitted in conjunction with the briefing on a summary
17 judgment motion in this case?

18 A. Yes.

19 Q. That was the summary judgment motion directed to the
20 issue of inequitable conduct; correct?

21 A. Yes.

22 Q. And if you would turn to the last page, --

23 A. Yes.

24 Q. -- is that your signature there?

25 A. Yes, it is.

1 Q. And you declared under penalty of perjury that the
2 foregoing is true and correct; is that right?

3 A. That's correct.

4 Q. If I can turn your attention now back to paragraph --
5 this is on page six. Are you with me on page six?

6 A. Yes.

7 Q. In paragraph 25, you're discussing the Board of
8 Appeals opinion that was rendered on July 5th, 1994, and
9 then continuing to paragraph 27, you state: Upon receiving
10 this unfavorable opinion, Jones submitted a file-wrapper
11 continuation application."

12 Do you see where I've read?

13 A. Yes.

14 Q. But as we've just seen, the file wrapper continuation
15 application was actually filed over a year prior to the
16 issuance of the Board's opinion; is that correct?

17 A. That's correct.

18 Q. So this paragraph 27 of your declaration is incorrect.

19 A. It's in error. I didn't check the dates. I
20 apologize.

21 Q. And when you made this error in your declaration, you
22 weren't intending to deceive the Court in any way, were you?

23 A. No. The fact of the file wrapper continuation
24 application being filed was correct. The fact of an
25 unfavorable opinion was correct. But the "upon" was not

1 correct.

2 Q. So any suggestion that the reason for filing the file
3 wrapper continuation was the subject matter of the opinion
4 is incorrect; is that right?

5 A. That's correct.

6 Q. Okay. Let's turn to tandamine.

7 Now, you mentioned that at some point, Mr. Jones
8 no longer was involved in the prosecution of the '590
9 patent. You understand that's because he had retired at the
10 end of 1996; correct?

11 A. I don't know whether he retired or not.

12 Q. Now, you talked about references that have been cited
13 by the European Patent Office in prosecution of a European
14 counterpart application, and you discussed the MPEP and its
15 discussion of citation of references identified during
16 foreign prosecution.

17 Now, the MPEP does not require that attorneys
18 indiscriminately submit all Y references that are cited by a
19 foreign Patent Office, does it?

20 A. Generally speaking, the practice is to submit all Y
21 references. In fact, they submit the entire search report.

22 Q. But there's --

23 A. But the rule says or the manual says that it has to be
24 material prior art. The general assumption is is that a Y
25 reference is material.

1 Q. But if it's not material, then there's no requirement
2 to submit it; correct?

3 A. That's correct.

4 Q. Okay. If I could ask you, the slides that we saw
5 during your direct examination; were you involved in putting
6 those slides together?

7 A. Yes.

8 Q. And you had put together a timeline. And my copy of
9 the slides are not numbered, but I believe it to be maybe 45
10 or 46, if we could have that put up on the screen, it's the
11 complete timeline.

12 Yes, that's the one.

13 Now, if I can direct your attention to the June
14 26th, 2000 box, where you state that there was a rejection
15 in the European Patent Office prosecution; do you see that?

16 A. Yes.

17 Q. If I can direct your attention to your binder Volume
18 2, and tab 18, --

19 A. I'm sorry, you said binder Volume 2 and tab 18?

20 A. That's correct.

21 Q. Okay.

22 Oh, I apologize. I apologize. It should be
23 Volume 3.

24 A. All right.

25 Q. I'm sorry.

1 A. I have that.

2 Q. Okay. Is this the June 6th, 2000 rejection that
3 you've identified on your timeline?

4 A. Yes.

5 Q. Okay. And if I can turn your attention to the second
6 page with the Bates numbers ending in 43.

7 (Off the record discussion)

8 Q. While you're finding that, let's take this slide down.

9 THE COURT: Well, he's got this.

10 THE WITNESS: I have a page, but --

11 Q. To give us some context, let's pull up the European
12 search report, which is DTX-211, and the second page of that
13 contains the references identified by the European Patent
14 Office?

15 A. Yes.

16 Q. And this tandamine reference is the last one on the
17 list; is that correct?

18 A. Yes.

19 Q. Okay. And let's go back to tab 18.

20 A. I have that.

21 Q. Plaintiff's Trial Exhibit 914.

22 A. Yes.

23 Q. Now, on the second page, in paragraph one, the
24 European Patent Office is saying -- this is a document you
25 considered in your work on this matter; correct?

1 A. Yes.

2 Q. And you understand that the tandamine reference was
3 identified as D-4 by the European Patent Office?

4 A. Correct.

5 Q. And you understand that the European Patent Office was
6 using T as an abbreviation for tomoxetine?

7 A. Yes.

8 Q. And here, the European Patent Office is saying:
9 "Since tomoxetine is a norepinephrine reuptake inhibitor,
10 the teaching of D3 and D4 directed to SRI cannot be taken
11 into consideration." Correct?

12 A. Correct.

13 Q. So this is not a rejection over the tandamine
14 reference; correct?

15 A. The -- I think -- you may be right there. Correct.

16 Q. Now, in fact, there was a previous rejection by the
17 European Patent Office; correct?

18 A. Could you point me to that?

19 Q. I'm going to have to ask you to move to another
20 binder. It's binder 1, tab two, and this is DTX-215.

21 THE COURT: It's on the screen. It may be easier
22 for you to deal with that, because that witness chair is --
23 the witness area is small.

24 Q. Let's turn to the second page -- I'm sorry, the third
25 page, and if we can blow up the screen beginning with

1 paragraph three.

2 Here, the European Patent Office is saying:

3 "According to D3 -- " -- which was another reference -- " --
4 a serotonin reuptake inhibitor (hereinafter referred to as
5 SRI), is effective in the treatment of ADHD."

6 Do you see where I've read?

7 A. Yes.

8 Q. And then in the last sentence, the European Patent
9 Office examiner says: "Likewise, tandamin, another SRI, has
10 been reported to be effective in the treatment of ADHD as
11 well." Correct?

12 A. Yes.

13 Q. But tandamine was not reported to be an SRI, was it?

14 A. That's correct.

15 MR. CLEMENT: Objection, Your Honor. I think this
16 is getting technical again.

17 THE COURT: Yes. Again, we're back to where
18 you've having him testify now as a chemist.

19 BY MR. BURWELL:

20 Q. Do you -- you assert that the tandamine reference was
21 material to the patentability of the '590 patent; correct?

22 A. I assert it's material because it was a Y reference,
23 and an examiner may have found something in there that he
24 wanted to know about.

25 Q. So you're not relying on the content of the reference

1 itself.

2 A. No, other than -- there is content in there, but I'm
3 not sufficiently skilled to be able to pick it out.

4 Q. If I can turn your attention to tab 17 of your binder,
5 PTX-913, and we can blow this up on the screen as well.

6 THE COURT: If he doesn't have to use the binders
7 I'd like him --

8 MR. BURWELL: Okay.

9 THE COURT: -- only because he's in a very cramped
10 space there, and it's very difficult to use them.

11 MR. BURWELL: I'll try to direct these to be blown
12 up on the screen.

13 THE COURT: Yes, if you have the ability to put
14 them up, technology be faster.

15 Q. If we can call up the first paragraph.

16 Now, do you recognize this as the response by
17 Lilly to the European Patent Office's June 6th rejection?

18 A. Yes.

19 Q. If I can turn your attention to the second page, the
20 second full paragraph, beginning five lines from the bottom
21 of that paragraph, there's a sentence that starts: "The
22 Applicants believe that D4 -- " -- which you understand is
23 the tandamine reference -- " -- is not particularly relevant
24 to the patentability of the present invention, claiming the
25 use of a structurally distinct compound, for use in the

1 manufacturing of a medicament which is useful for treating a
2 wholly different disease state than that disclosed by the"
3 tandamine reference.

4 Do you see where I've read?

5 A. Yes.

6 Q. And then they go on to state: "The Applicants cannot
7 locate the teachings in reference to D4 that suggest to the
8 artisan that tandamine is effective for treating ADHD." Do
9 you see that? Do you see where I've read?

10 A. Yes.

11 Q. And then going to tab 18, PTX 914, if we can blow that
12 up on the screen, this is the European Patent Office
13 document that you had discussed in your time line, and on
14 the second page, we see the European Patent Office states,
15 as we saw before -- if you blow up the first paragraph --
16 "The use for tomoxetine in the treatment of ADHD could not
17 have been derived from any of D1 through D4, alone or in
18 combination."

19 Do you see where I've read?

20 A. Yes.

21 Q. Okay. Now, you talked about Mr. Titus's submission of
22 European -- references cited in European search reports in
23 other patent prosecutions before the U. S. Patent Office.

24 A. Yes.

25 Q. If I can direct your attention to PTX-300, which is at

1 tab six of your binder, this is one of the prosecution
2 histories that you identified as one where Mr. Titus had
3 submitted references that had been cited in a European
4 Patent Office search report after issuance of a notice of
5 allowance; correct?

6 A. That's correct.

7 Q. If I can turn your attention to page 81, and this is a
8 document showing that Mr. Titus submitted references cited
9 by the European Patent Office on July 24, 1999; is that
10 correct?

11 A. Yes.

12 Q. And turning to page 84, this is the European search
13 report that lists the references that Mr. Titus submitted in
14 this instance; is that correct?

15 A. That's correct.

16 Q. And the tandamine reference is not listed on this
17 European search report, is it?

18 A. That's correct.

19 Q. And Mr. Titus did not submit the tandamine reference
20 to the Patent Office in connection with this application,
21 did he?

22 A. That's correct.

23 Q. Okay. If I can direct your attention now --

24 A. He didn't cite it.

25 Q. -- to PTX-301.

1 A. PTX-301.

2 Q. Tab seven of your binder.

3 Turning your attention to page 70, -- oh, I'm
4 sorry. Let me take you back to the first page of this
5 document.

6 This is the prosecution history of the patent
7 application directed to the use of tomoxetine to treat
8 oppositional defiant disorder that you discussed in your
9 direct examination as another instance in which Mr. Titus
10 had submitted references cited by the European Patent Office
11 to the U. S. Patent Office. Do you understand that?

12 A. That's correct.

13 Q. If I can turn your attention to page 70, --

14 A. Yes.

15 Q. -- this is the information disclosure statement that
16 was submitted by Mr. Titus, and it shows it was submitted on
17 July 15, 1999. Do you see that?

18 A. Yes.

19 Q. If I can turn your attention to page 73, this is the
20 European search report that lists the references that were
21 cited by Mr. Titus to the Patent Office in this application;
22 correct?

23 A. Yes.

24 Q. And the tandamine reference is not listed on this
25 European search report, is it?

1 A. That's correct, it's not cited.

2 Q. And if you notice, all of the references that are
3 listed on this European search report are X references; is
4 that correct?

5 A. Yes.

6 Q. And just to close the loop on the previous document we
7 looked at, going back to PTX-300 at page 84, this is the
8 conduct disorder patent application, and again, all of the
9 references cited by Mr. Titus that had been identified in
10 the European search report were X references; is that
11 correct?

12 A. That's correct.

13 Q. And what is an X reference?

14 A. An X reference is a reference that by itself would
15 make the subject matter obvious or unpatentable.

16 Q. Can we scroll down to the bottom of the form?

17 The identification of the letters used to describe
18 references is down at the bottom, and you agree that an X
19 reference is one that the European Patent Office considers
20 particularly relevant if taken alone; correct?

21 A. Correct.

22 Q. Let's go back to your declaration submitted in
23 connection with the summary judgment briefing. That's
24 Volume 4, tab number 2.

25 If I can direct your attention to paragraph 48,

1 located on page nine.

2 A. Yes.

3 Q. Actually, let's go back to paragraph 47 and 48 and
4 show those together.

5 In this part of your declaration, you are talking
6 about how Mr. Titus had received the corresponding European
7 search reports in the counterpart to the '590 application;
8 correct?

9 A. Yes.

10 Q. And then in paragraph 48, you say you also understand
11 from Mr. Titus's deposition testimony that on prior
12 occasions when he had received European search reports on
13 other applications to atomoxetine, he had removed the
14 applications from allowance in order to cite the European
15 search report.

16 Do you see that?

17 A. Yes.

18 Q. But as we've just seen, the evidence that you've cited
19 did not occur on prior occasions, it was on subsequent
20 occasions; correct?

21 A. That's correct. The paragraph said it's my
22 understanding, and we're not testifying in court to that, it
23 was on prior occasions.

24 Q. I'm sorry, I didn't hear the last part.

25 A. It says it was my understanding, and it was my

1 understanding at that time, but when we were making the
2 timelines realized that's not the case, and so we changed
3 it.

4 Q. Okay. So your understanding was incorrect at the time
5 you made this declaration.

6 A. That's correct.

7 Q. Okay. If we can turn to tab 14, which is in binder
8 three, it is PTX-770, and page 944381.

9 Now, this is a document that you talked about on
10 your direct examination where Mr. Titus had submitted the
11 European search report that had been issued by the European
12 Patent Office in the ADHD prosecution -- prosecution of the
13 European counterpart to the ADHD patent. This is Mr.
14 Titus's submission -- well, this is the submission of the
15 search report to the Canadian Patent Office; correct?

16 A. Yes.

17 Q. If we can turn to page 944369, and the text at the
18 bottom right-hand portion of the page states that, in the
19 third paragraph: "It would be to an applicant's advantage
20 to furnish particulars of the prior art cited in respect of
21 the corresponding applications before the United States
22 Patent Office and European Patent Office when such
23 information becomes available. Furthermore, in order to
24 assist in the examination of this application, a copy of all
25 non-patent citations would be appreciated."

1 Do you see where I've read?

2 A. Yes.

3 Q. And do you understand that Mr. Titus testified in his
4 deposition that he cited the European Patent Office search
5 reports to the Canadian Patent Office because of this
6 request by the Canadian Patent Office?

7 A. This says to his advantage, they would like to have
8 that, and it's the same thing the United States Patent
9 Office says. Now we're treating the European patent -- the
10 Canadian Patent Office with deference, and we're saying to
11 the United States Patent Office we're not going to send you
12 that, we're not even going to explain why we're not sending
13 it to you.

14 Q. Do you understand that Mr. Titus had testified that it
15 was submitted to the Canadian Patent Office as a matter of
16 course?

17 A. As a matter of what?

18 Q. As a matter of course?

19 A. As a matter of course? He submits -- submitted the
20 other references that were foreign search reports as a
21 matter of course, but somehow he didn't send it, this one
22 particular one, to the U. S. Patent Office as a matter of
23 course. That's all it would have taken, to just submit it.

24 MR. BURWELL: Your Honor, one moment while I
25 confer?

1 THE COURT: Yes.

2 MR. BURWELL: Your Honor, would now be a good time
3 to break for lunch.

4 THE COURT: Where do you stand with respect to
5 your questioning?

6 MR. BURWELL: My colleagues would like to suggest
7 a few additional questions.

8 THE COURT: Is it going to be much in the way of
9 redirect?

10 MR. CLEMENT: I don't think I have anything, Your
11 Honor, so far.

12 THE COURT: How many more questions do you have?
13 Do you need time?

14 MR. LIPSEY: I was going to suggest, if possible,
15 if we could take a moment to confer over lunch, we're
16 probably done, or very close to it, I would think.

17 THE COURT: All right. My problem is, is this
18 witness going to be staying around?

19 MR. CLEMENT: I think he's scheduled to leave
20 today.

21 MR. LIPSEY: I mean, if he's going to be excused
22 with no redirect, I would not ask him to stay.

23 THE COURT: We shouldn't keep the witness hanging
24 around if he's not otherwise going to have to be here if
25 it's just a matter of a few more questions.

1 MR. LIPSEY: If they represent there is no
2 redirect, as a courtesy to Mr. Goolkasian, I'll --

3 THE COURT: I just want the record to be clear I'm
4 not precluding you from asking more questions, but I'm
5 trying to be, you know, aware of people's time.

6 MR. CLEMENT: We have no redirect.

7 THE COURT: Well, you've got that.

8 MR. LIPSEY: Then we're done, too, Your Honor.

9 MR. BURWELL: Then no further questions.

10 THE COURT: Look at that. Look at what I've saved
11 you.

12 (Laughter)

13 THE COURT: Can the witness step down?

14 MR. BURWELL: Yes.

15 THE COURT: You're done, sir. Thank you very
16 much.

17 Go ahead. Do you want to move exhibits into
18 evidence? In the normal circumstances, this would go in in
19 your case, but I guess there's no objection about evidence
20 going in on whomever's case, correct?

21 MR. CLEMENT: We don't have any objection to that,
22 Your Honor.

23 THE COURT: All right. Go ahead.

24 MR. BURWELL: I would like to move into evidence
25 Plaintiff's Exhibit 913, Plaintiff's Exhibit 914,

1 Defendants' Exhibit 215, and Plaintiff's Exhibit 912, if it
2 was not already mentioned.

3 THE COURT: Any objection?

4 MR. CLEMENT: Can we have a representation those
5 are the ones we saw during the testimony?

6 MR. BURWELL: That's correct.

7 MR. CLEMENT: No objection.

8 THE COURT: Into evidence.

9 (Plaintiff's Trial Exhibits 912, 913 and 915 and
10 Defendants' Trial Exhibit 215 marked in evidence)

11 THE COURT: Anything else?

12 MR. BURWELL: That's all, Your Honor. Thank you.

13 THE COURT: You may step down, sir.

14 THE COURT: Which witness do we have next?

15 MR. PARKER: Dr. James Johnson, Your Honor.

16 THE COURT: And the witness is here?

17 MR. PARKER: He is, Your Honor.

18 THE COURT: All right. As I told you, we're going
19 to go until 3:30 today.

20 MR. PARKER: That's correct, Your Honor.

21 THE COURT: All right. It's about quarter after
22 12. We'll see you back here at quarter after one.

23 MR. PARKER: Thank you, Your Honor.

24 THE COURT: Thank you.

25 (Luncheon recess taken)

1 A F T E R N O O N S E S S I O N

2 THE COURT: Be seated.

3 There's been a slight change in my schedule.

4 We're going to go to six today --

5 (Laughter)

6 THE COURT: We're going to break at three, not

7 3:30. Okay?

8 Next witness.

9 MR. PARKER: Thank you, Your Honor.

10 Your Honor, my name is Tom Parker. I'm here for
11 the Defendants.

12 Mr. Clement would like to address the Court.

13 MR. CLEMENT: I forgot yesterday to introduce My
14 colleague, Dr. Andrea Wayda, who is going to be seated at
15 counsel table for this witness.

16 THE COURT: All right. Fine.

17 MR. PARKER: Your Honor, Defendant calls as its
18 next witness Dr. James Johnson.

19 MR. LIPSEY: And, Your Honor, the witness will be
20 handled on our end by my partner, Mr. Bajefsky.

21 THE COURT: Fine.

22 Up here, sir.

23 MR. PARKER: Your Honor, may we provide you with
24 the witness binders at this time?

25 THE COURT: Sure.

1 THE COURT CLERK: Placing your left hand on the
2 bible, raising your right hand:

3 J A M E S R O B E R T J O H N S O N, called as a witness
4 on behalf of the Defendants, and having been duly sworn,
5 testified as follows:

6 THE COURT CLERK: Please be seated.

7 Please state your name, spelling it for the
8 record.

9 THE WITNESS: My names is James Robert Johnson,
10 J-a-m-e-s, R-o-b-e-r-t, Johnson, J-o-h-n-s-o-n.

11 DIRECT EXAMINATION

12 BY MR. PARKER:

13 Q. Dr. Johnson, would you just please state your name and
14 address for the record, please?

15 A. James Robert Johnson, 2129 East Glen Alden Drive,
16 German town, Tennessee, 38139.

17 Q. Now, Dr. Johnson, you have been retained by Defendants
18 as an expert in this case?

19 A. Yes.

20 Q. Dr. Johnson, you've been practicing in the area of
21 pharmaceutical dosage form development and drug delivery
22 system development for over 40 years. Is that fair?

23 A. Yes.

24 Q. Dr. Johnson, do you have your CV in front of you? I'd
25 like you to just have that handy because I'd like to go over

1 your background.

2 A. Okay.

3 MR. PARKER: Your Honor, may I just approach the
4 Court with two copies of the CV?

5 THE COURT: Sure.

6 Q. Dr. Johnson, can you just briefly tell us a little bit
7 about your educational background?

8 A. Yes. I have a B.S. in pharmacy from the University of
9 Minnesota in 1962, and I have a Master's and a Ph.D. in
10 pharmaceutics at the University of Minnesota College of
11 Pharmacy with a minor in physical chemistry.

12 Q. I'm sorry, did you mention a Master of Science in
13 pharmaceutics from the University of Minnesota?

14 A. Yes.

15 Q. And when did you receive that degree?

16 A. 1968.

17 Q. Now, by whom are you currently employed?

18 A. University of Tennessee College of Pharmacy.

19 Q. And what position do you hold at the University of
20 Tennessee?

21 A. I'm associate professor.

22 Q. And how long have you had that position?

23 A. I've been working with the University of Tennessee for
24 approximately 25 years. For the first 10, I was a
25 volunteer, where I had developed some courses and worked

1 with graduate students and was on thesis committees, and
2 then for the last 15 years, I've been an employee, employed
3 as associate professor.

4 Q. Now, are you currently doing any research at the
5 University of Tennessee?

6 A. We're doing a variety of things. We have six graduate
7 students. We have a visiting colleague from FDA in China
8 who's going to be with us for a year who's going to be
9 working on dosage forms and raw materials. We have a
10 research associate, and we have an instructor that I work
11 with, and we've recently added two more -- an assistant
12 professor that's going to work with our group, and we've
13 added two more students.

14 Q. Dr. Johnson, are you doing any research on injectable
15 sustained-release dosage forms?

16 A. We've worked on injectable sustained-release -- depot
17 research -- research on depot systems since approximately
18 1992.

19 Q. Are you also conducting research on development of
20 soluble systems for high-dose drugs?

21 A. Yes.

22 Q. And could you just briefly explain just generally?

23 A. These high-dose drugs are becoming increasingly
24 important because many of the new drugs are even more
25 insoluble than some of the old ones, so what we've been

1 doing is trying to find new ways to solubilize these and
2 then put them in a format where you can easily use these to
3 formulate either tablets or other dosage forms.

4 Q. Now, Dr. Johnson, do you do any teaching at the
5 University of Tennessee?

6 A. Please repeat.

7 Q. Do you do any teaching at the University of Tennessee?

8 A. Yes. Over the last 15 years, I taught in the
9 parenteral drug development course, and I've also lectured
10 in a preformulation course that we offer, and we've also
11 developed a tableting course that we've taught 34 times in
12 the last 12 years to more than a thousand people.

13 Q. Do you teach any courses concerning injectable drugs?

14 A. Pardon me?

15 Q. Have you taught any courses --

16 A. Yeah, I've taught in the parenteral drug course.

17 Q. All right. Now, you just mentioned something about a
18 tablet course. Could you just tell us a little bit about
19 that?

20 A. It's a course that we offer to industry people three
21 times a year, and we offer it to the graduate students and
22 we offer it to the pharmacy students, and it -- it really
23 tries to prepare people who may be entering the area about
24 preformulation, formulation, granulation, tableting,
25 coating, and analytical support and review of what else you

1 might do to evaluate the products.

2 Q. Thank you, Dr. Johnson.

3 Now, let's just talk a little bit now about your
4 experience in the industry.

5 Can you please tell us about your most recent
6 industry employment?

7 A. Most recent was Schering-Plough.

8 Q. And you were there from what period of time?

9 A. From 1976 to 1996.

10 Q. And did you hold various positions at Schering-Plough?

11 A. I had held various positions. I started as a manager
12 in '76 and held various positions. The last 14 years, I was
13 vice president of R & D in one area or another.

14 Q. And were you also -- I believe you were vice president
15 of R & D development for the pharmaceutical and I believe
16 sun care groups.

17 A. It was -- we managed the development of over the
18 counter drug products, the sun care products, and the Dr.
19 Scholl products.

20 Q. Were you also vice president of the new technologies
21 group?

22 A. Yes.

23 Q. AND what was that? Can you tell us a little bit about
24 that?

25 A. We explored a variety of new technologies to try to

1 determine if we could find delivery systems which would be
2 appropriate for our products.

3 Q. Now, just how long were you at Schering-Plough, again?

4 A. Twenty years.

5 Q. Twenty years?

6 A. Twenty.

7 Q. And what types of drug development work did you do at
8 Schering-Plough?

9 A. We -- in the pharmaceutical area, we developed all
10 kinds of dosage forms, including suspensions, tablets,
11 coated gums, aerosols, various types of products. And --

12 Q. So were you employed in any preformulation work?

13 A. Yes, I had a preformulation group.

14 Q. And can you just define for us, for the Court, what do
15 you mean by preformulation?

16 A. This is where we typically try to examine the
17 characteristics of the drug substance and compatibility that
18 it would have in various systems, in either solvent systems
19 or aqueous systems.

20 Q. Did you oversee the formulation group?

21 A. Yeah, I had at least three or four formulation groups
22 at various times. We generally divided these into expertise
23 in tablets, liquids, topical products, aerosols.

24 Q. And what's the difference between -- you described
25 preformulation. What did you mean by formulation group?

1 What did they do?

2 A. The formulation group is where we were actually
3 putting the drug in a dosage form which we can either test
4 or utilize in some way.

5 Q. Now, during your tenure at Schering-Plough, I believe
6 you described, and correct me if I'm wrong, that basically,
7 you have the responsibility of giving the quote-unquote
8 green light with respect to the -- before any product was
9 launched at Schering. Can you just describe what that
10 responsibility entailed?

11 A. For -- it's probably over 10 years, but what we did
12 is, we would -- before we would approve any product for
13 release, we would put together all the data in a binder and
14 we would compile all of our preformulation work, our
15 formulation work, our analytical work, our safety work, our
16 tests, any clinical testing work we might have done and
17 stability work, and I'd review that and make a determination
18 whether we had completed all the work necessary.

19 Q. Now, did Schering-Plough also look to you for
20 expertise in terms of -- with respect to just drug
21 development in terms of what would be involved, what would
22 be needed, the cost, expenses, resources, things of that
23 nature?

24 A. Yes, I would typically be involved pretty early in the
25 process to try to estimate how long it would take us to

1 complete projects, the amount of effort it would require,
2 the complexity it would require.

3 Q. Now, prior to your employment at Schering-Plough, did
4 you have any other industry experience?

5 A. I worked at Ayerst Laboratories for eight years.

6 Q. And can you just tell us what titles you held at that
7 company?

8 A. I was senior pharmacist, group leader, section head.

9 Q. And, I'm sorry, were you section head of the
10 pharmaceutical development group?

11 A. It was pretty much the solids group, where we did the
12 solid formulations, the standard release formulations and
13 suspensions. We also looked at some other liquid systems,
14 but it was basically those dosage forms.

15 Q. And so what were the years that you were employed by I
16 believe it's Ayerst?

17 A. '68 to '76.

18 Q. So approximately how many years of industry experience
19 do you have in drug development?

20 A. Twenty-eight.

21 Q. And were those years directed primarily to developing
22 various dosage forms?

23 A. Yes.

24 Q. Do they involve pharmaceutical drugs?

25 A. Yes.

1 Q. Now, have you ever served as a consultant, and if you
2 did, can you briefly describe the activities you have
3 undertaken as a consultant?

4 A. We served periodically as a consultant to various
5 companies who called, and we'd conduct projects for them.
6 We're currently working on a sustained-release project for a
7 company. We have done delivery-system products which were
8 also delayed or time-release for oral use, like bypass the
9 stomach and were selectively for release in the intestine,
10 and various projects like that.

11 I've also been principal investigator for six
12 small business grants that -- I think five were NIH, one was
13 FDA.

14 Q. And can you just tell us what was the nature of those
15 -- what was the subject matter --

16 A. They were various things. One was a tableting
17 project. We made tablets, capsules -- or not capsules, it
18 would be tablets in a solution, and a chewable tablet.

19 Another one was where we -- in fact, three of them
20 were a sustained-release depot injection project. Another
21 one was a sustained-release injection product for opiate
22 addiction. We've also done a variety of other projects in
23 opiate addiction. We've developed several systems which are
24 very difficult to abuse. We're looking for abuse,
25 drug-abuse-resistant systems.

1 Q. Now, Dr. Johnson, are you a member of any scientific
2 societies?

3 A. The American association of Pharmaceutical Sciences
4 and the Controlled Release Society.

5 Q. Now, given the number of years you have in the
6 industry -- you've had in the industry and also in academia,
7 do you consider yourself a person having substantial
8 knowledge about the various disciplines required to develop
9 a pharmaceutical dosage form and the amount of time,
10 resources and efforts necessary for formulating those dosage
11 forms?

12 A. Yes.

13 Q. Now, again, Dr. Johnson, based upon all your years of
14 experience in the industry and academia, do you consider
15 yourself a person who is highly knowledgeable about
16 immediate and controlled-release drug delivery systems?

17 A. Yes.

18 Q. Tablets?

19 A. Yes.

20 Q. Oral solutions?

21 A. Yes.

22 Q. Suspensions?

23 A. Yes.

24 Q. Injectable solutions?

25 A. Yes.

1 Q. Depot injections?

2 A. Yes.

3 Q. Suppositories?

4 A. Yes.

5 Q. Topical drug delivery systems?

6 A. Yes.

7 Q. And I'm sure they are others, but those -- are there
8 others as well that I have not mentioned? You don't have to
9 mention them. Just, are there others?

10 A. There probably are. We did an awful lot of different
11 dosage forms.

12 Q. Now, you used the word "pharmaceutics" I believe in
13 connection with your experience. What is pharmaceutics?
14 What does that mean?

15 A. When I took it, it meant, it was basically application
16 of physical chemistry to pharmaceutical dosage systems.

17 Q. Now, in your experiences, Dr. Johnson, did you have an
18 occasion to work with physicians in terms with respect to
19 drug development?

20 A. Yes, most of our products were tested in some way or
21 another. We did -- I had a small group, which we'd do a lot
22 of the topical evaluations and testing, and then we
23 generally worked with various physicians for other testing.

24 Q. And did you have an occasion to work with clinicians?

25 A. Yes.

1 Q. Any others in other disciplines that you had to
2 interact with?

3 A. I actually worked with quite a few of the Schering
4 people in both their chemistry, their legal department, and
5 other areas.

6 Q. Now, while you were at Schering, were you responsible
7 for overseeing technical disciplines, and, if so, can you
8 please describe the groups that you were responsible for
9 overseeing?

10 A. Well, over the years, I managed a number of groups.
11 When I started, I believe I had approximately 10 people. We
12 were basically a formulation group, and a stability group,
13 and I think we had the packaging group, and then eventually
14 it grew to roughly 100, 110 people, where I was managing
15 virtually all aspects of the drug development except the FDA
16 interactions and the clinical department.

17 Q. All right. Were you also responsible for overseeing
18 the physical pharmacy group at Schering-Plough?

19 A. Yes. I had a physical pharmacy group -- well, we
20 called it that for a while, then I think we changed the name
21 to preformulation. That I had a variety of preformulation
22 groups in solids, liquids, topical products, aerosols.

23 Q. Did that group have any responsibilities with respect
24 to characterizing various dosage forms?

25 A. Well, they would prepare the dosage forms and then

1 they would develop test techniques to allow us to
2 characterize them and test them.

3 Q. Now, have you yourself participated in any clinical
4 studies of animals and humans?

5 A. Yes, we currently did a rather large number of samples
6 last year in rats with buphenophrine depot injections.

7 Q. And in your years of experience, do you have any
8 participation -- we know you're not a physician, but did you
9 have any involvement or participation in connection with
10 human studies, any development of a dosage form?

11 A. We would be involved in the design of a number of
12 these studies, especially for topical evaluation. We were
13 involved in let's say start-up, trying to figure out how you
14 would go about testing sustained-release systems.

15 MR. PARKER: Your Honor, at this time, Defendants
16 would like to tender Dr. Johnson as an expert in the field
17 of pharmaceutical dosage form development and drug delivery
18 system development.

19 THE COURT: Any objection?

20 MR. BAJEFSKY: No, Your Honor.

21 THE COURT: He may so testify as an expert.

22 MR. PARKER: Thank you, Your Honor.

23 BY MR. PARKER:

24 Q. Now, Dr. Johnson, did Defendants ask you to provide an
25 opinion -- let me strike that.

1 Did Defendants ask you to provide any opinions on
2 any issues relating to this case?

3 A. Yes.

4 Q. And what was that issue?

5 A. I was asked to give an opinion on whether one of
6 ordinary skill in the art could complete the claims of the
7 '590 patent without undue experimentation.

8 Q. Now, in rendering and reaching that opinion or
9 conclusion, did you review or rely on any materials?

10 A. Yes.

11 Q. And can you just -- what materials did you rely on?

12 A. I looked at the '590 patent, some early -- early
13 patents relating to formulations and some of the chemistry.
14 I also looked at some supporting publications. I looked at
15 some literature references. And I also used my own opinion.

16 Q. I'm sorry, what was that?

17 A. I also used my own opinion based on my experience.

18 Q. Now, in making this assessment with respect to undue
19 experimentation, did you consider a series of factors?

20 A. I considered the Wands factors.

21 Q. Well, us lawyers call them the Wands factors. I
22 understand you're familiar with that. But which factors do
23 they entail?

24 A. They entail the nature of the invention, the breadth
25 of the claim, relative skill in the art, the amount of

1 guidance disclosed by the patent, the presence or absence of
2 working examples, the predictability of the art, the
3 quantity of the experimentation necessary, and the state of
4 the prior art.

5 Q. All right. So in reaching your opinion which you'll
6 provide later on, these were the factors that you considered
7 in doing so?

8 A. Yes.

9 Q. Now, you mentioned the date January 11th, 1995. What
10 is the significance of that date?

11 A. That's the date of submission of this '590 patent.

12 Q. And what role, if any, did that date play in your
13 analysis?

14 A. I tried to evaluate it these factors based on what was
15 the technology at that or prior to that date.

16 Q. Okay, Dr. Johnson. Let's look at the first Wands
17 factor, which is the nature of the invention.

18 Now, you testified just before that you considered
19 all the Wands factors, so let's turn to the nature of the
20 invention.

21 And what conclusions did you reach with respect to
22 that factor?

23 A. I tried to determine what is the nature of events. To
24 me, it meant that it was the method of -- I tried to
25 determine the nature of the invention by -- and to me, it

1 meant that it was a method of treating ADHD by administering
2 an effective amount of atomoxetine to a patient in need of
3 the treatment.

4 Q. And did you also consider to any extent the methods of
5 administration of atomoxetine?

6 A. Yes. I reviewed the patent and tried to determine the
7 theory and examples or any other information or instruction
8 for how it would be administered.

9 Q. Now, with respect to ADHD, do you have an
10 understanding of or did you have -- did you consider the
11 manner in which ADHD is treated?

12 A. Yes. It's known to be a chronic disorder, and it
13 requires extensive treatment for more than -- like probably
14 four to six weeks to determine efficacy, and that makes
15 determining whether or not a product is active much more
16 difficult.

17 Q. Now, with respect to this factor, the nature of the
18 invention, did that have any effect in your ultimate
19 conclusion?

20 A. Yes. It made -- to me, it means that the product is
21 more difficult to complete, and undue experimentation is
22 likely.

23 Q. Now, in your analysis, Dr. Johnson, did you consider
24 the breadth of the claims of the '590 patent?

25 A. Yes.

1 Q. And what conclusions, if any, did you reach in that
2 connection, in that regard?

3 A. Well, claim 1 is very broad, and it's a method of
4 treating attention deficit/hyperactivity disorder comprising
5 administering to a patient in need of such treatment an
6 effective amount of atomoxetine.

7 Claims 2 to 16 depart from this and depend upon
8 this, and they are generally there to narrow the claim.

9 But the scope is very broad as to dosage forms
10 they might utilize in administering atomoxetine.

11 Q. Dr. Johnson, if you would just speak up a little
12 louder.

13 A. I don't know if I can. I can move the chair.

14 Q. All right. Thank you.

15 What do you mean by that you felt that the claims
16 were very broad? And I'm speaking with respect to claims 1
17 through 16. Is that what you meant, they were very broad?

18 A. Yes.

19 Q. Okay. What did you mean by they were very broad?

20 A. They don't really specify a dosage form that you have
21 to use and they really allow any -- any sort of dosage form
22 to be used, and I just think that expands the scope.

23 Q. Did you consider whether or not the claims place any
24 limitation on the form of atomoxetine?

25 A. I don't see -- I didn't see any limitation on those

1 claims.

2 Q. Now, is there anything in the specification that you
3 -- when you reviewed the patent, was there any language in
4 there that played a role or part in your analysis of the
5 breadth of the claims?

6 A. Yes.

7 Q. And can you refer to that? You can see it on your
8 screen or up on the slide.

9 A. Yes, those are the -- they really first talk about all
10 pharmaceutical forms, such as tablets, capsules, suspensions
11 and the like, and that's one route of administration. Then
12 they also talk about other types of forms, such as
13 injectable solutions, depots and suppositories and the like.
14 And these are dosage forms that really are not orally
15 administered, and absorption amounts are quite different.

16 Q. Well, let me ask you, did you consider the phrase at
17 all "and the like"? Did that have any meaning to you? Did
18 that have any significance to your evaluation of the scope
19 of the claim?

20 A. Yes.

21 Q. What was that?

22 A. It indicated to me that they really weren't limiting
23 the dosage forms to tablets, capsules or suspensions for
24 oral use, or they were not limiting those other ones
25 mentioned on the slide with regard to dosage form.

1 Q. Okay. And where in the patent is that located? Is
2 that referred to in the slide there? Can you identify where
3 that is located?

4 A. That's in the '590 patent, column 2, lines 28 to 30.

5 Q. Now you mentioned that -- I believe you were referring
6 to, with respect to the language we were just referring to
7 in the patent that that was broken or that came -- that
8 identified pharmaceutical dosage forms into two categories?

9 A. Yes, we had oral, and then we have non-oral.

10 Q. And what's the difference between the two?

11 A. The difference is in the -- one of the main
12 differences is the impact in dosage. When the drug would
13 pass through the mouth, stomach and liver, it may be subject
14 to the first-pass effect, and indeed, with this drug, it is.
15 So the problem with this drug happens to be that there's
16 extensive metabolizers and there's slow metabolizers. So
17 dosing is not simple.

18 With the non-oral dosage forms, the depot
19 injections pass through tissue into the bloodstream.
20 Transdermals pass through the tissues into the bloodstream.
21 Suppositories pass through the mucosa of the rectum into the
22 blood stream. Injectables introduce directly into the
23 bloodstream. So what we don't know is, we don't know what
24 the dose would be for these non-oral dosage forms. We have
25 no reference point as to treatment of any individual with

1 these dosage forms.

2 Q. All right. Now, when you say we don't know, what are
3 you referring to?

4 A. We don't know -- we don't know the dose that would be
5 administered.

6 Q. The specification doesn't provide that for you?

7 A. No.

8 Q. Now, just staying with the scope, the breadth of the
9 claims, Dr. Johnson, just to give us a sense -- well, let me
10 back up.

11 You mentioned extensive metabolizers and poor
12 metabolizers of atomoxetine; do you recall that?

13 A. Yes.

14 Q. Can you just generally explain what that means?

15 A. That means that the blood levels for people who
16 metabolize slow versus fast will have --

17 MR. BAJEFSKY: Objection, Your Honor. He's
18 talking about clinical issues, and he is not competent to
19 testify about those issues.

20 MR. PARKER: Your Honor, the whole issue about
21 extensive metabolizers and poor metabolizers, that's in the
22 references that he considered and that he relied upon. He
23 certainly is competent to understand the -- he didn't
24 actually conduct the studies, he wasn't a clinician, but he
25 understands the data that was generated and the conclusions

1 that were drawn in that particular paper.

2 THE COURT: I think that was part of the issue of
3 the in limine motion also as to whether or not he conducted
4 this.

5 I'm going to allow him to testify.

6 BY MR. PARKER:

7 Q. Just generally, based on your understanding of the
8 literature, what did you understand extensive metabolizers
9 and poor metabolizers to mean?

10 A. It means that the blood levels will vary widely
11 between these two groups.

12 Q. How widely were they between the two groups?

13 A. Half-life was like four and a half hours with the fast
14 metabolizers and up to around 17, 18 with the slow. But
15 this is a very important factor to consider when you're
16 making any kind of delayed-release formula or
17 sustained-release formula.

18 Q. So for us lay people to understand, so basically, poor
19 metabolizers would just have it in their system, the drug, a
20 lot longer than the extensive metabolizers. Is that fair?

21 A. Say that again.

22 Q. So just to kind of put it into lay language, that the
23 poor metabolizers, the difference between poor metabolizers
24 and extensive metabolizers with atomoxetine is that the poor
25 metabolizers just have the drug in their system for a longer

1 period of time.

2 A. The half-life is about 17 hours to let's say go from
3 100 to 50, if that would happen to be the blood level.

4 Q. Now, just staying on the scope of the claim, the
5 breadth of the claim, okay, did you give considerations of
6 the types of dosage forms that could fall within the scope
7 of that -- of claims 1 through 16 of the '590 patent?

8 A. Yes, this is a list of representative dosage forms
9 that we considered, and includes sustained release
10 solutions, suspensions, fine granules, orally disintegrating
11 tablets, sustained-release oral tablets, sustained-release
12 oral capsules, depot injections, transdermal delivery
13 systems, thin films, injectable solutions, delayed-release
14 tablets and capsules, delayed-release and sustained-release
15 tablets and capsules where you would coat the matrix, and
16 chewable, could be chewable tablets or chewy, gooey tablets
17 that you might make for children.

18 Q. All right. We'll be going over some of these in some
19 detail, but where did you get this list? I'm sorry, where
20 did you get some of these dosage forms?

21 A. This was abstracted from -- we took this from the
22 Lilly list of line extensions.

23 Q. Now, was that Exhibit DT -- Defendants' Exhibit 162 in
24 your binder?

25 A. Yes.

1 MR. BAJEFSKY: Your Honor, we object to the use of
2 this document and any testimony based on it. It was, in
3 fact, cited in his expert report for a single purpose, and
4 that is that the atomoxetine had a bitter taste. It is
5 nowhere else mentioned in his report. He does not rely on
6 it any place in his report as part of his opinion, and when
7 he raised it on his own in the deposition, in his
8 deposition, I asked him what he knew about it, and he didn't
9 know anything about it. He said he was guessing what it was
10 and he had no factual basis for any of the testimony that he
11 was giving.

12 MR. PARKER: That's absolutely not true. He
13 testified for about a half hour on this document during his
14 deposition. He gave an extensive discussion exactly about
15 what it meant. I mean, he was in the industry for 30 years.
16 He knew exactly what this document was. It's a line
17 extension document. Lilly considered a whole slew of
18 various dosage forms.

19 Now, it was also, Your Honor, listed as materials
20 that he reviewed and relied upon, discussed at his
21 deposition, and it was cited in his deposition, and he was
22 deposed on it.

23 THE COURT: Let me see the part in the deposition
24 that you say where he says he doesn't know anything about
25 it.

1 MR. BAJEFSKY: Okay.

2 Can we bring it up?

3 Page 247.

4 THE COURT: And hand me a copy of the deposition.

5 MR. BAJEFSKY: Okay.

6 If we start at page 247, Your Honor, and his
7 answer beginning on line 11.

8 THE COURT: Yes, let me just review this.

9 Chuck, let me have the basis to counsel's
10 objection read back.

11 (Record read)

12 THE COURT: And is it your position that in
13 support of the claim that he didn't know anything about it,
14 he was guessing about it is that which is contained --

15 MR. BAJEFSKY: Well it's on 248.

16 THE COURT: I'm reading -- is that which is
17 contained in pages 247 and 248?

18 MR. BAJEFSKY: 247 and 248, and then on 254.

19 THE COURT: Hold on.

20 Now, I'm going to allow him to testify. I don't
21 think that the deposition that I just read supports that
22 objection, and I think under these circumstances, too, he
23 uses the words, I guess with this, I guess with that. But I
24 think that this goes to the weight of the testimony and not
25 the admissibility.

1 I'll allow it. Let's go.

2 MR. BAJEFSKY: Your Honor, one other point, if I
3 may make one other point on it.

4 THE COURT: Okay, but usually, once I rule, that
5 means we stop and we move forward. I don't go back and
6 re-rule.

7 What is it?

8 MR. BAJEFSKY: This is a 2007 document. He said
9 his opinion was based on what happened in 1995. This has
10 nothing to do with the state of the art in 1995, Your Honor.

11 THE COURT: What do you say to that?

12 MR. PARKER: Well, Your Honor, in their brief,
13 Lilly says at about -- well, Plaintiffs say: "There is no
14 evidence that atomoxetine or its salts has any chemical or
15 physical characteristics that would present any special
16 problem in formulating dosage."

17 This document is inundated with statements that
18 contradict that position.

19 Now, the fact that they're saying now in a 2006
20 document about all these technical issues with respect to
21 tomoxetine, they also were present, they had to have been
22 present in 1995. So -- and right now, as part of
23 Dr. Johnson's testimony right now, he's simply looking at
24 this document, saying, look, Lilly assessed at least these
25 dosage forms, using these as examples what is in the scope

1 of the claims.

2 THE COURT: I'm going to allow it. I'm going to
3 allow it. And there's no jury here. If after
4 cross-examination or otherwise it can be demonstrated to me
5 that this would be inappropriate, I always have the
6 opportunity to reject it.

7 Okay. Let's go.

8 BY MR. PARKER:

9 Q. Okay. So, Dr. Johnson, so again, we're on the breadth
10 of the claims, and what you have presented in slide eight,
11 which is various dosage forms, these dosage forms are the
12 ones that you feel fall within the scope of the claims of
13 the '590 patent?

14 A. Yes.

15 Q. And these were dosage forms that you extracted from
16 Lilly document DXT-162?

17 A. Yes.

18 Q. We have lots to cover, but you mentioned first-pass
19 effect. Could you just tell us what that means? Just
20 generally.

21 A. Generally, what it means is, when the drug is taken
22 orally, it has to be dissolved, and then it will pass
23 through the stomach, intestine, and the liver will
24 metabolize it.

25 Q. Now, is there an example of a dosage form that would

1 not have first-pass effect?

2 A. Dosage forms which are let's say topically or rectally
3 or injected directly into the blood. The depot injections
4 won't be affected in that manner.

5 Q. Now, Dr. Johnson, with respect to DTX-162, is this
6 where you were able to obtain the list of dosage forms?

7 A. Yes.

8 Q. And I'm referring to STPAT 769571.

9 All right. Now, are there other dosage forms that
10 you feel also fall within the scope of the claim of the '590
11 patent?

12 A. We looked at a couple more here where we thought that
13 you possibly could do sublingual tablets, you could do
14 lozenges, ointments, or other topical systems, or you could
15 do other liquids, like elixirs.

16 Q. Now, these dosage forms existed in 1995, did they not?

17 A. Yes.

18 Q. And what about these dosage forms?

19 A. Yes.

20 Q. Now, you talked about --

21 THE COURT: You know, you're saying "these dosage
22 forms." I don't know what this is going to look like on the
23 record. Nobody's going to know what "these dosage forms"
24 are. I think we're going to have to -- I'm certainly not
25 going to remember.

1 Q. With respect to the dosage forms that you just
2 testified as to, that you just testified about --

3 THE COURT: Well, all I think you have to do is to
4 say what slide you're referring to.

5 Q. With respect to slide eight, Dr. Johnson, were these
6 dosage forms available as of January 1995?

7 A. Yes.

8 THE COURT: And that's DTX-162.

9 MR. PARKER: Correct.

10 THE COURT: Go ahead.

11 Q. And, Dr. Johnson, with respect to the dosage forms
12 that are listed on slide 11, were they, too, also available
13 as of January 1995?

14 A. Yes.

15 Q. All right. Now, let's just -- we just talked a little
16 bit about dosage forms that fall within the scope of the
17 claims.

18 Did you reach any conclusions with respect to the
19 form of atomoxetine in terms of what would fall within the
20 scope of the claim?

21 A. They state that tomoxetine is a well-known drug and is
22 regularly used as a salt, and salts are included here in the
23 term tomoxetine to be used.

24 Q. Now, is there a difference between tomoxetine salt
25 form and tomoxetine base, and, if so, can you tell us what

1 those differences are?

2 A. Tomoxetine base is an oily liquid, and tomoxetine
3 salts would generally be a solid.

4 Q. Now, with respect to the potential salt forms for
5 atomoxetine, were you able to find or locate any --

6 MR. BAJEFSKY: Objection, Your Honor. There's
7 nothing in his expert report about alternative salt forms.

8 MR. PARKER: He never asked -- well, let me back
9 up, Your Honor. There's a little background here.

10 Initially, our expert for formulation was Dr. Atul
11 Shukla, --

12 THE COURT: Right.

13 MR. PARKER: -- who passed away.

14 THE COURT: Right. He adopted his report.

15 MR. PARKER: He adopted his report.

16 In Dr. Shukla's report, he mentions in his report
17 that the claim is not limited by any form of atomoxetine.
18 It includes all salt forms.

19 Now, whether or not he asked him during his
20 deposition, I don't recall. But it's in the report.

21 MR. BAJEFSKY: There's no listing of salt forms.
22 He mentions that it covers alternative salt forms. There is
23 no suggestion that there are all these salt forms that were
24 available anyplace in the deposition -- I'm sorry, in the
25 expert report. There was no reason to inquire about it in

1 the deposition.

2 MR. PARKER: We cited to the '081 patent in the
3 expert report, I believe, and that's where the salt forms
4 were I believe identified.

5 MR. BAJEFSKY: But not in any way, Your Honor,
6 that had any bearing whatsoever on the salt forms. The
7 portions that were cited to did not deal with the salt
8 forms, Your Honor.

9 THE COURT: Well, show me where in his report
10 and/or adoption of the report that he mentions this.

11 MR. PARKER: Well, we do have '081.

12 THE COURT: Maybe the witness can do it. He might
13 be more familiar with his report than counsel, so maybe you
14 should ask him if he can point that out to you.

15 THE WITNESS: It's actually pointed out in -- the
16 '590 patent includes atomoxetine and all salts, and that's
17 pretty wide open. And so that to me would mean
18 pharmaceutically acceptable salts of tomoxetine, and it's my
19 understanding that would fall within the scope. They don't
20 identify. Some of these products would require salts which
21 are insoluble, and you would go to a list like this and pick
22 out some you thought would be insoluble and try to use
23 those. That's what I'd do.

24 THE COURT: I'd like to see the part of the report
25 that refers to this, that you claim refers to this.

1 MR. PARKER: I'll find that in a second, Your
2 Honor.

3 Just for a little more background, too, the salt
4 forms came from another patent owned by Eli Lilly, which is
5 the atomoxetine compound patent which we referred to, the
6 '081 patent. Now that was attached as Exhibit 4 to
7 Dr. Shukla's report. And I know, given a few more minutes,
8 I will be able to find the portion.

9 THE COURT: Go ahead.

10 MR. PARKER: So let us just -- why don't we go
11 back to this concept or this matter in a second.

12 BY MR. PARKER:

13 Q. All right. So, Dr. Johnson --

14 THE COURT: So we're going to another topic for
15 the moment.

16 MR. PARKER: We're going to go to another topic.
17 At some point, I have to -- I know it's around here. I want
18 to go back and extract as opposed to doing it on the fly.

19 THE COURT: All right. Then until that occurs,
20 I'll sustain the objection.

21 Q. Now, with respect to Wands factor three, Dr. Johnson,
22 relative skill of those in the art, did that at all play any
23 role in your analysis?

24 A. Yes.

25 Q. And did you yourself -- and when you were studying all

1 these materials and these factors, did you have an
2 understanding as to what one skilled in the art would be?

3 A. On my next slide, I have -- that reflects what we
4 tried to assess as somebody skilled in the art as of that
5 date, and somebody that would have three to five years'
6 experience in developing dosage, a particular dosage form; a
7 degree in pharmacy, a B.S. degree in pharmacy or a closely
8 related field, and the skilled formulator would have to be
9 sophisticated enough to be able to consult with other
10 disciplines, like analytical chemists, biopharmaceutical
11 scientists and physicians.

12 Q. Now, with this particular factor, the one skilled in
13 the art, did that have any effect on your ultimate
14 conclusion at all?

15 A. Yes. Many of these are sophisticated dosage forms
16 which I think would be very difficult for this person to
17 prepare or develop without undue experimentation.

18 Q. Now, let's go on to the next factor, the amount of
19 guidance disclosed in the patent. Did you at all consider
20 that as part of your analysis?

21 A. Yes.

22 Q. And does the patent talk about any dosage form?

23 A. Yes. Column 2, 7 through 33, there is some comments
24 about the dosage forms as we reflected on before, and the
25 guidance reports to discuss you may dose it as tablets,

1 capsules, suspensions and the like, and other dosage forms
2 which are not oral, such as sustained-release systems,
3 injectable solutions, suppositories and the like.

4 Q. Now, does the patent also identify a dose?

5 A. Well, they give dosage ranges, but it's a little
6 difficult to tell because they don't say -- they say it's
7 probably a salt for this -- these capsules, but they don't
8 say -- as I recall, they don't say that it's for a
9 hydrochloride salt or any salt, and if you're trying to give
10 the dose, you really need to define what the salt would be.
11 So if you're giving -- if it's a hydrochloride salt and you
12 say it's a hundred milligrams, that would only be about 80,
13 85 milligrams of base. So they really didn't define it very
14 well.

15 Q. Well, do they also -- in the specification, does it
16 tell you -- does it correlate the dose range that's
17 identified in the patent, does it correlate that with any
18 particular dosage form?

19 A. They don't say.

20 Q. Now, based on your review of the prior art, did you
21 have an understanding as to where the dose ranges may have
22 come from?

23 A. I assume it had to be from the -- some of the early
24 studies on -- for depression.

25 Q. And how is the atomoxetine administered in those

1 studies?

2 A. It was administered in the capsule, but there's no
3 definition of what the capsule was, other ingredients. I'm
4 not -- I don't believe it would be -- I don't even know
5 whether or not they set it up to atomoxetine hydrochloride.

6 Q. Now, with respect to the other dosage forms, the depot
7 injections, suppositories, the injectable solutions, so
8 there's nothing in the specification in your view that links
9 those dosage forms with that dose range?

10 A. No.

11 Q. Now, does the patent talk about -- does the patent
12 discuss anything about the physical characteristics of the
13 compound atomoxetine?

14 A. There's very little description about the compound.
15 It just sort of defines what it is.

16 Q. Can you tell us where the patent is located?

17 A. It's line 54 to 59, and in column 2, lines 1 to 3.

18 Q. And so when you refer to lines 54 to 59, were you
19 referring to column 1?

20 A. Yes.

21 Q. All right. And what's discussed there?

22 A. It just states that "Tomoxetine is a well-known drug,
23 the chemical name is -- it's phenylpropylamine. And "It is
24 regularly used as a salt, and salts are included in the term
25 tomoxetine as used here." Again, they really don't define

1 which salt is used here in this patent.

2 Q. So now with respect to discussing the dose form, the
3 dose, and the physical characteristics of the drug itself,
4 is what's up on your slide, is that about the extent of what
5 the patent states in connection with that subject matter?

6 A. With regard to formulation, they're trying to
7 determine what kind of -- how to make something, yes.

8 Q. And did you come to any conclusions with respect to
9 that disclosure in the specification in terms of your
10 analysis?

11 A. Yes, I thought it would make it difficult for someone
12 to do this without undue experimentation.

13 THE COURT: You found it difficult to do without
14 experimentation?

15 THE WITNESS: Undue experimentation.

16 THE COURT: Undue experimentation.

17 Q. Now, the claims also use the phrase "effective
18 amount." Do you recall that?

19 A. Yes.

20 Q. Now, is there anything in the specification -- when
21 you review the specification, did you see anything
22 indicating as to what would constitute an effective amount
23 for any particular dosage form?

24 A. They don't -- they don't relate the effective amount
25 that they proscribe to any dosage form.

1 Q. Now, if you move to the fifth Wands factor, the
2 presence or absence of working examples in the patent, did
3 you consider that factor in your analysis?

4 A. Yes.

5 Q. Now, in your review of the patent, did you come to any
6 conclusions as it relates to this particular factor?

7 A. Yes. There are no working examples in the '590
8 patent.

9 Q. Now, working examples, what does that -- what did you
10 believe that to mean?

11 A. It means to me that you like to see a starting point,
12 you like to see -- if they're treating somebody, you really
13 need to know a close or an approximate dose -- you need to
14 know, you'd like to see some working examples of how you
15 make the dosage form that they claim would be useful to use.
16 You'd like to see some ranges. You'd like to see some tests
17 run on the product, in other words, either stability or
18 dissolution rates, and these are commonly used.

19 Q. And was any of that information in the specification?

20 A. No.

21 Q. Now, how did the fact that there existed -- that the
22 '590 patent disclosed no working examples, what effect did
23 that have, if any, on your analysis?

24 A. It means that you have to start very early in the
25 process and would favor undue experimentation.

1 Q. Okay. Now, let's go with the last three Wands
2 factors, which maybe will take some time. This is the
3 predictability of the art, the quantity of experimentation
4 necessary, and the state of the prior art.

5 Dr. Johnson, we're going to take these all
6 together. Is that okay with you?

7 A. Fine.

8 Q. Probably be a lot faster; right?

9 A. We hope so.

10 (Laughter)

11 Q. Okay. Now, how did you look at these factors when you
12 were -- in your analysis? How did you implement these
13 factors in your analysis?

14 A. I looked at them in the context of the last 40 years.
15 After taking a look at these dosage forms to see how
16 predictable is it, how long would it take, what's the state
17 of the prior art, do I have to reinvent the wheel, is
18 anything there to help me, and I try to just ascertain
19 whether or not -- what it's going to take to do these
20 things.

21 Q. Now, let's just talk a little bit, just briefly, you
22 have -- with respect to immediate-release capsules and
23 tablets containing atomoxetine hydrochloride, did you reach
24 an opinion as to whether or not it would require undue
25 experimentation?

1 A. Yes.

2 Q. And what was your opinion?

3 A. I decided that you could probably say or you could --
4 you could say that the immediate-release capsule tablet
5 would be stable containing atomoxetine hydrochloride.

6 Q. Can you just tell us in general what's the basis of
7 your opinion in that regard?

8 A. Well, we go back -- we went back to some of the prior
9 art, and there were capsules and tablet formulations listed
10 which in my experience I believe would work. It's a dry
11 system. There's no -- there's no -- going to be little or
12 no moisture there. So it's most likely that it would be
13 fairly stable.

14 Q. Now, let's go through the -- can you tell us what's on
15 the right-hand side?

16 A. Yes. On the right side, these are a representative
17 list of dosage forms that I thought would -- I would
18 consider nonenabled, like depot injections, transdermal
19 patches, suppositories, suspensions, injectable solutions,
20 sustained release formulations, and a variety of others.

21 Q. And in reaching that conclusion, and we'll over go
22 over that in detail, did you consider the quantity of
23 experimentation?

24 A. Yes.

25 Q. And the predictability?

1 A. Correct.

2 Q. And you also considered the prior art as well?

3 A. Correct.

4 Q. All right. Why don't we just start off with depot
5 injections?

6 Now, this was a slide that was prepared pursuant
7 to your direction, was it not, slide 22?

8 A. Pardon me?

9 Q. This was a slide prepared based on your supervision
10 and direction; correct?

11 A. Right. I dictated the process.

12 Q. All right. And does this slide, Dr. Johnson,
13 accurately reflect, again, based on your knowledge and
14 experience, the steps one skilled in the art would undertake
15 to prepare a depot injection?

16 A. Yes.

17 Q. Can you please explain, what is a depot injection?

18 A. A depot injection is where you put the drug in some
19 sort of matrix and inject it, either under the skin or in
20 the muscle, typically.

21 Q. What's the purpose of a depot injection?

22 A. You do it so that you can just dose periodically, you
23 don't have to dose every day, or if it has a five-hour
24 half-life you don't have to dose twice a day, or -- like
25 that. So you can maybe give weekly injections or injections

1 that might last a month or up to six months.

2 Q. Are there any depot injections on the market today
3 that you're aware of?

4 A. I have a list, but I didn't count them, but I think
5 there's on the order of 25 or so. Some are veterinarian,
6 and a number of these are human.

7 Q. But again, can you give a specific example of any
8 depot injections on the market today?

9 A. One that we've looked at was Maltrexel (ph). In fact,
10 we had the NIH grant for Maltrexel depot injection, and we
11 could sustain it on the order of two weeks to a month, but I
12 don't think our technique was suitable. It was also a
13 product, the Maltrexel injection, and Alchemy (ph) designed
14 it, and I know it took them well over five years.

15 Q. Now, I believe you used the phrase, at least maybe
16 during the deposition, but viable dosage form. Does that
17 sound familiar to you?

18 A. Yes.

19 Q. And what is a viable dosage form?

20 A. I use it as a -- in the context of a dosage form
21 sufficiently refined so that I'm willing to put it in
22 people.

23 Q. So let's just back up. How does that relate at all to
24 your analysis? And if you can put it in context of the
25 schematic with depot injection. How does that play into

1 your analysis?

2 A. Well, we -- you just don't put it in a glob of wax and
3 inject it. You really have to -- you really have to do
4 sufficient preformulation, formulation work and safety work
5 to know that you can put it into people with a high degree
6 of safety.

7 Q. Now, but with respect to the formulation steps that
8 you've laid out in slide 22 and 23, is the end result the
9 preparation of a viable dosage form?

10 A. Yes. It's something that --

11 Q. Now, in these schematics, we're not talking about a
12 dosage form approved by the FDA for commercial sale;
13 correct?

14 A. No. No.

15 Q. Would a viable dosage form be one that would enable
16 someone to -- would enable a physician to practice the
17 claimed invention?

18 A. Yes.

19 Q. And we'll get into how, where that step fits into the
20 process.

21 Now, can you please explain to the Court the
22 process that a person of ordinary skill as of January 11th,
23 1995 would have followed in preparing a depot injection
24 comprising an effective amount of atomoxetine for the
25 treatment of ADHD?

1 A. Yes.

2 Q. Please do.

3 A. On our slide, we put a number of the steps that we
4 would do. I've done two columns. On the right side, on the
5 right side, I just used the base, because it's possible we
6 could do this with the base. Another side would most likely
7 have to do inside the salt. So that would be -- either one
8 of these would require a certain amount of work to try to
9 characterize them and purify the raw material and develop
10 that so we're in a position we could actually develop these
11 products.

12 Q. All right. So let me just -- where were you? Were
13 you on -- with your pointer, can you point us to where you
14 are on this process?

15 A. Well, right at the top, so -- what I was going to do
16 is maybe briefly I can go through one of these, and then if
17 you want, you can ask me questions to clarify it, or I'll do
18 it --

19 Q. No, no, I just mean with the selection.

20 MR. BAJEFSKY: Your Honor, can we have the
21 question-answer format rather than a narrative answer so I
22 can object, if necessary?

23 THE COURT: Yes, you can certainly -- we need a
24 question-and answer-form. But sometimes the response is an
25 explanation. I thought you were asking him about the

1 process --

2 MR. PARKER: Yes.

3 THE COURT: -- or how he did something.

4 Well, I don't know how he answers that other than
5 to go through it. It seems to me to make an amount of
6 sense.

7 A. Okay. So I'll just briefly go through the process to
8 show what we're talking about and then answer your question.

9 Q. Well, before you do that, Dr. Johnson, is there any
10 information in the prior art that atomoxetine can be used in
11 a depot injection?

12 A. No.

13 Q. So having the '590 patent in hand, why would someone
14 have to go through all these steps?

15 A. Because there's no information to help.

16 Q. And there's nothing in the prior art, to your
17 knowledge?

18 A. Not that I'm aware of.

19 Q. So why don't we begin with selecting a form of
20 atomoxetine?

21 A. I'm aware that you can also take a base like this and
22 put it in certain solvents, and the base, what we're going
23 to do is, we're going to purify the base. We will put it in
24 some sort of -- disperse it in some sort of system, and then
25 we would need to look at the purity, stability,

1 compatibility and solubility in this vehicle. And if we
2 want to take this and try to see whether it would be
3 sufficiently long, in other words, if we dose it once a
4 week, it might work, we can put it in a hydrotropic system,
5 solution, after we understood that it might be stable in
6 that system, and then we would develop a variety of these
7 solutions, we would do dissolution on the systems as well as
8 stability, and once we got a system we thought was -- would
9 work, we would go to the next page.

10 Q. Okay. So, again, so you've already talked about the
11 -- you're over here. We're talking about selecting the form
12 of atomoxetine, and you just described selecting the --
13 using the base as a potential --

14 A. Right. I'm trying to just go down the simplest system
15 that I can think of.

16 Q. Okay.

17 THE COURT: Well, if this is the simple system --
18 (Laughter)

19 THE COURT: Because I'm confused. You're telling
20 us now the way you would go about this?

21 THE WITNESS: Your Honor, I'm telling you about --
22 this is the way we did go about it.

23 THE COURT: Okay.

24 Q. Well, Dr. Johnson, would this be a way that one of
25 ordinary skill in the art would have gone about it in your

1 opinion in 1995 if they had to --

2 A. He would have gone through most of the same steps, I
3 believe.

4 Q. Okay. Now, with respect to the compatibility,
5 stability, purity, --

6 A. Right.

7 Q. -- okay, and what's the purpose of conducting this
8 type of testing?

9 A. We want to characterize the raw material to know what
10 the solubility and stability are so we know what other
11 things we could mix with it. We would typically take the
12 base and mix it with a variety of solvents and determine if
13 it was stable.

14 Q. And why does one skilled in the art need to conduct
15 crystal purity testing?

16 A. Well, in this case, we won't have a crystal, but we
17 still have to make sure that our oil in this case, which we
18 believe it would be, would be pure.

19 Q. And how does one skilled in the art go about
20 conducting this type of testing?

21 A. You typically would find ways to make sure that the --
22 you use mass spec or some other way, carbon hydrogen
23 analysis, nitrogen analysis to make sure that you're getting
24 close to 100-percent pure, you don't have the composition
25 product.

1 Q. Why does one skilled in the art conduct stability
2 testing?

3 A. Because you can't give people unstable product.

4 Q. And how does one go about conducting stability
5 testing?

6 A. Usually you put the form that you want tested at
7 elevated conditions and you subject it with oxygen or light,
8 heat, and analyze it after periodic intervals.

9 Q. And now, again, for compatibility testing, why would
10 someone want to carry on compatibility testing?

11 A. Because sooner or later you're going to have to mix it
12 with something to dose it, so you want to have -- determine
13 what range of materials you might want to work with.

14 Q. Now, you have a number of arrows -- and I'm referring
15 to slide 22 -- you have a number of arrows that are
16 associated with the blue diamonds up top: Solubility,
17 compatibility and stability and purity testing. Do you see
18 that?

19 A. Yes.

20 Q. What were you trying to illustrate with those arrows?

21 A. That many of these steps are iterative, and you hope
22 you guess right, but typically, you don't.

23 Q. And how many cycles -- based on your experience, how
24 many cycles would you expect?

25 A. In the top row, you would probably have at least one

1 cycle, going from preliminary formulation, in vitro
2 dissolution testing, you might have many cycles. Most
3 likely, you would have more than two.

4 Q. Now, would you consider these an aspect of -- with
5 respect to this aspect of the process, development process,
6 would you consider any of that routine?

7 A. No.

8 Q. Why not?

9 A. Well, most of the decisions are going to be complex.
10 Some of the mechanics of let's say putting oil in a beaker
11 or something like this is not complex, but the
12 interpretation certainly is.

13 Q. Now, could a person of ordinary skill in the art
14 predict without conducting any solubility, stability,
15 compatibility and purity tests whether or not the base would
16 be suitable for depot injection?

17 A. No.

18 Q. Nothing in the literature that would help you, would
19 help one skilled in the art? Is there anything in the
20 literature?

21 A. There are a few things that might actually help you,
22 but not -- you would still have to do the work.

23 Q. Now, based on your experience, how long do you believe
24 it would take one skilled in the art just to carry out and
25 conduct that first aspect of the development process?

1 A. What's the first aspect?

2 Q. Well, the one we're talking about, the solubility,
3 compatibility, stability, and purity testing.

4 A. That's probably three to six months.

5 THE COURT: Three to six months?

6 THE WITNESS: Correct.

7 Q. Now, can you explain, with respect to selecting the
8 form of atomoxetine, is also a choice that one skilled in
9 the art would have, and that's dealing with insoluble salt
10 selection; right?

11 A. Yes.

12 Q. And why does it have to be insoluble?

13 A. Because atomoxetine hydrochloride is too soluble. You
14 really wouldn't be able to sustain release of that for any
15 length of time. With Maltrexel, they made a stearate salt,
16 and that's one of the things that helped them. In addition
17 to making the stearate salt, they encapsulated it.

18 Q. So atomoxetine hydrochloride, that would -- in your
19 view that would not be an appropriate salt form?

20 A. No. It wouldn't work.

21 Q. Now, over here, you also have listed solubility,
22 compatibility, stability --

23 A. We've actually tried Maltrexel hydrochloride, and it
24 really didn't -- you couldn't sustain it for any length of
25 time.

1 Q. And that was actually a depot injection?

2 A. Yes.

3 Q. Now, over here in the process, you have solubility,
4 compatibility, stability, and crystal purity testing. Do
5 you see that?

6 A. Yes.

7 Q. Now, is that the same level of -- with respect to the
8 quantity of experimentation that you described in connection
9 with the base with those same tests, is it the same for the
10 insoluble salt selection?

11 A. It would probably be more, because you would most
12 likely select two -- try to make at least two or three
13 different salts. So you'd be doing this three times, I
14 mean, in parallel, but you'd be doing it with multiple
15 salts.

16 Q. So over here when you have the arrows in the yes and
17 noes that are indicated on slide 22 up there by the purple
18 diamond solubility, compatibility, stability and purity,
19 what were you trying to convey there?

20 A. That -- two things, actually. I probably would have
21 three more boxes for the different salts, but most of the
22 time you're not going to be able to guess at the solubility,
23 so you have to do the work. You might have to go back and
24 do it over again and choose different salts.

25 Q. So one of ordinary skill in the art would not be able

1 to predict an appropriate insoluble salt form without
2 conducting these tests. Is that your opinion?

3 A. That's my opinion.

4 Q. And how long would it take one of ordinary skill in
5 the art in your view to complete this phase of the
6 development?

7 A. I would think that would maybe take more than -- more
8 than six months.

9 Q. Now, once you've selected a potential insoluble salt
10 form of atomoxetine, what is the next step one skilled in
11 the art would conduct?

12 A. We would -- we would try to put in a system suitable
13 for injection.

14 Q. Can you just -- is this where --

15 A. That would be our preliminary formulation stage.

16 Q. So it would be a preliminary formulation and excipient
17 selection?

18 A. Right.

19 Q. Now, underneath, you have four boxes and it says
20 microparticles, rods --

21 A. Right.

22 Q. -- the AQ, -- which is aqueous -- suspensions?

23 A. Right.

24 Q. -- and oil suspensions?

25 A. Right.

1 Q. Can you tell us what those are?

2 A. Those are just some examples of different systems that
3 you might choose to do this. I think what we followed
4 through with here was the aqueous suspensions because that's
5 been used for many years and it's a common system.

6 Q. So now what would one of ordinary skill in the art do
7 at this point in the development process?

8 A. You would try to -- try to make this insoluble salt a
9 suitable particle size and a formulation good enough so that
10 it wouldn't settle so fast that you can't inject it. You
11 would do -- probably choose multiple particle sizes because
12 in this system, that's really going to control your rate of
13 dissolution, and you look at the stability and you try to
14 get this in sufficient state that you could do the
15 dissolution steps with predictability and consistency.

16 Q. Okay. Now, you also mentioned settling tests. What
17 does that -- why does one need to carry out --

18 A. If it's a suspension and you're drawing it out of a
19 vial, it's got to stay in suspension long enough without
20 settling so you can actually get an accurate dose.

21 Q. And how would one go about carrying out a settling
22 test?

23 A. Well, there are many ways that you can do it. You can
24 do it -- actually, the easiest way to do it is just take
25 vials and take multiple doses out of the vial periodically.

1 That's probably the easiest way to do it.

2 Q. And just tell me, why would one of ordinary skill in
3 the art carry out the particle size test and stability test?

4 A. The particle size is pretty important in this model so
5 that you can adjust the solution rate of the drug in the
6 depot injection into the body so that we can control how
7 fast it's going to dissolve and go into the body.

8 Q. Now, again, you have arrows and you have the yes and
9 noes going up and down. What were you intending to convey
10 there?

11 A. That you probably will have to repeat this multiple
12 times.

13 Q. Now, based on your experience -- well, could one of
14 ordinary skill in the art predict the outcome of these
15 tests?

16 A. No.

17 Q. They would have to carry them out?

18 A. Yes.

19 Q. Now, would you consider these tests, the particle size
20 test, the settling test and stability test to be routine in
21 connection with the development of a depot injection at this
22 stage?

23 A. Well, the mechanics of weighing and measuring are not
24 -- not difficult, but interpretation certainly will be.

25 Q. Now, what do you mean by the interpretation?

1 Interpretation of what? The data?

2 A. Well, yes, and you're going to -- from all these
3 experiments, you always get data, get data, get data. And
4 what do I do with it? Can I make sense out of it? Can I
5 put the pieces together and actually proceed forward? So
6 that's always the hard part, always.

7 Q. And making judgment calls based on the data, would
8 that be something that you would consider difficult?

9 A. Yes.

10 Q. And how long would it take for one of ordinary skill
11 in the art in your opinion to carry out this stage of the
12 development?

13 A. Maybe another three to six months. I mean, try to --
14 all this stuff, maybe you try to -- could do it in less than
15 a year. If I was, I'd probably be lucky.

16 Q. Excuse me?

17 A. I'd try to do it in less than a year, but it's going
18 to be one plus or minus.

19 Q. Now, again, there's no information out there in the
20 prior art that would be able to deal specifically with
21 atomoxetine in connection with depot injection; right?

22 A. Not specifically with atomoxetine.

23 Q. Now, with stability testing, you mentioned, just so we
24 can kind of move along, you mentioned that you would look at
25 the -- I guess the interaction of the formulation in

1 connection with heat, light, and oxygen?

2 A. Right.

3 Q. Would that be the same here as well?

4 A. Yes. Yes.

5 Q. Now, with respect to the quantity of experimentation
6 that you just described with the insoluble salt here, would
7 that be relatively the same for the base?

8 A. It would probably be -- probably be more.

9 Q. More? Why is that?

10 A. You mean at that point or --

11 Q. At this point over here. I'm showing you the particle
12 size test, and the corresponding test of solubility --

13 A. They'd be similar.

14 Q. They'd be similar?

15 A. Similar.

16 Q. And the same with respect to predictability: Would
17 that be the same, would they be the same, roughly?

18 A. They'd be equally unpredictable.

19 Q. And again, as far as the prior art, there's -- any
20 information in the prior art with respect to atomoxetine
21 base and how it would react in a depot injection?

22 A. No.

23 Q. And in terms of time, how long would it take one of
24 ordinary skill in the art to complete this aspect of the
25 development process?

1 A. Another three months plus. It's very difficult to get
2 these correlations of how fast it's going to dissolve in
3 some of these in vitro tests, and there aren't very many in
4 vitro tests. We're actually trying to develop a mechanistic
5 study of prediction. We have rat data and we have
6 dissolution data on these hydrophobic vehicles with bases
7 where we're starting to get some predictions. So in the
8 future, we're going to be able to do this quite a bit
9 faster. But at the time, we can't find anybody else who's
10 done it.

11 Q. But as of 1995 --

12 A. No. No.

13 Q. -- these types of tests weren't available.

14 A. No.

15 Q. Okay. Now, we did not go through, and I just want to
16 see if we can go through this real quickly, we didn't go
17 through microparticles, rods and oral suspensions in
18 connection with the insoluble salt, but would your testimony
19 be the same with respect to quantity of experimentation at
20 this portion of the development stage where you're leading
21 into the in vitro solution, multiple samples?

22 A. Yes, except that the preliminary formulation would be
23 expanded. That would be more difficult.

24 Q. In connection with microparticles?

25 A. Yes.

1 Q. What about, would it be the same for rods?

2 A. I believe so.

3 Q. And oil suspensions?

4 A. I believe so.

5 Q. And also, if you look to the base selection, you have
6 microparticles, rods, would that also be the same in terms
7 of the quantity of experimentation as you described it in
8 connection with the aqueous suspension?

9 A. Yes.

10 Q. So what's next for one of ordinary skill in the art?
11 Once they've conducted these tests, and I guess they've been
12 able to get something that's of a potential preliminary
13 formulation and excipient selection -- and before I begin,
14 what is an excipient?

15 A. It's an ingredient that we utilize in conjunction with
16 the active ingredient to make a dosage form.

17 Q. So is an excipient everything inside the pill, the
18 capsule?

19 A. It's everything else.

20 Q. Other than the active ingredient.

21 A. Right.

22 Q. And you say compatibility with excipients. What are
23 you referring to?

24 A. Well, you know, if it has an effect on pH, it may
25 cause it to precipitate; does it react with the drug.

1 Mostly things like that.

2 Q. So you look at whether or not the active ingredient is
3 -- if the active ingredient is incompatible with the
4 particular excipient, can you give us an example of what
5 could happen?

6 A. It would probably -- usually what you see in some of
7 these systems, certainly in sustained-release systems, if
8 you -- if you form a eutectic mixture, for example, it will
9 change the melting point. That's especially the problem
10 with suppositories or something like that.

11 Q. Okay. All right. Now, let's go to the -- again, with
12 the steps we were referring to, this is the particle size,
13 settling test, stability test, and over here, stability
14 test, solubility test, now, where are we going and tell us
15 where is it that -- based on this schematic, where is it
16 that one skilled in the art -- what does one skilled in the
17 art have to do next?

18 A. We refine the formulation so it would be suitable for
19 injection into an animal.

20 Q. Okay. So we're now from the in vitro dissolution,
21 multiple samples, we're now down to refining the
22 formulation?

23 A. Right. Right.

24 Q. Now, why are we refining the formulation? Why would
25 one of ordinary skill in the art refine the formulation?

1 A. We're going to have to refine it in terms of dose per
2 unit that we can actually inject or utilize to determine
3 whether or not it has activity.

4 Q. Okay. Well, let me just back up.

5 What do you mean by refine formulation?

6 A. Well, we'll modify it. In other words, we made the
7 solutions, stability at one percent or .5 percent. Now we
8 have to put a set amount of drug in a set amount of liquid,
9 in this case let's say, so we can actually dose it to an
10 animal.

11 Q. Okay.

12 A. So you have to refine it so you get the right amount,
13 and like with a rat, I can inject maybe half a ml or less.
14 So I have to put the dose that I'm looking for in that
15 quantity.

16 Q. So now focusing on the refined formulation aspect of
17 the development, you have identified five tests:
18 Syringeability, stability, in vitro dissolutions, sterility,
19 and injection site. Do you see that?

20 A. Yes.

21 Q. Now, syringeability, what is that? What does that
22 mean?

23 A. Well, we injected these from a syringe, so it has to
24 be able to pass through the needle and into the site where
25 we're injecting it.

1 Q. And how would one skilled in the art go about doing
2 that?

3 A. You may do it very simply by just picking up the
4 liquid and pushing it out, and if it doesn't take a lot of
5 -- a lot of strength, you might do something as simple as
6 that. Otherwise, we have a device where we can -- we can
7 calculate the pressure needed to expel the liquid over a
8 period of time.

9 Q. Now, what about stability testing? Is that the same
10 as you've discussed before -- Dr. Johnson, we have to make
11 sure -- when I finish, then you can begin.

12 With respect to stability testing, would you just
13 describe what type of tests those would entail?

14 A. Could you repeat the question?

15 Q. Stability testing; what does that entail?

16 A. What it would typically do for stability testing now
17 that we have changed the ingredients, we would confirm that
18 our stability assessments that were made in this first stage
19 are still -- still firm and correct.

20 Q. And in vitro dissolution testing?

21 A. Yes. We would repeat the in vitro dissolution at the
22 concentrations that we were actually going to utilize for
23 injection.

24 Q. And why would you have to repeat them?

25 A. Well, these tests at this point really aren't

1 predictive enough that we can tell, so we would do that
2 again.

3 Q. Now, what is sterility? What do you mean?

4 A. We have to make sure it's sterile. If it's a
5 solution, we can push it through .2 mic or a small filter
6 and that will probably be adequate as long as we prepare the
7 sample under sterile conditions. If it's a particle size,
8 let's say particulate matter is much more difficult. We may
9 radiate it or we may make sure that this -- we'll prepare
10 the powder sterilely and then we'll aseptically fill and put
11 the product together.

12 Q. Now, you have over there identified injection site.
13 What do you mean by -- can you just explain what you mean by
14 that?

15 A. What we want to evaluate is the injection site after
16 injection to determine whether or not we have any untoward
17 reactions to our drug, our vehicle, our system.

18 Q. And how would you go about testing that?

19 A. Usually we'll inject placebo vehicle, and we will
20 examine the site daily and we'll probably biopsy it at one,
21 three, five, seven days, depending on the length of time or
22 duration of injection that we think would be used.

23 Q. Now, you have again a series of arrows, yes and noes.
24 What is it that you were trying to convey there?

25 A. We're just simply trying to convey that many of these

1 steps are iterative. We don't always guess right.

2 Q. Now, do you have an understanding or at least do you
3 have an opinion as to how long it would take one of ordinary
4 skill in the art to carry out these series of tests in order
5 to begin any animal studies?

6 A. With some of these, with the base, we probably can do
7 this fairly quickly, like less than three months. With some
8 of these particulate matter, we've done it with insoluble
9 salt, I think it's considerably more difficult, so it's
10 probably more than that.

11 Q. And why would a salt be more difficult?

12 A. Well, you've gone to a particle, and this particle is
13 controlling your dissolution rate for the most part, and the
14 coating, that's an additional complex factor.

15 Q. And the particle size also, I believe you mentioned,
16 has an effect on sterility?

17 A. Well, it's -- it's more difficult to actually prepare
18 sterile powders than it is to sterilize the solution.

19 Q. Now, at this point, is there any indication whether or
20 not the base would be appropriate for depot injection, would
21 you know?

22 A. We have a decent idea of whether -- but it really all
23 depends on what kind of extent or magnitude of duration of
24 action we're trying to get. If the outline of the project
25 we're trying to do is going to be let's say two weeks to a

1 month, well, let's say more than two weeks, up to a month,
2 it's not likely that the base -- we're going to be able to
3 do that. That's not likely.

4 Q. Now, could a person of ordinary skill in the art
5 predict without conducting any of these tests whether or not
6 a particular salt form of the atomoxetine or the base form
7 would be suitable for the animal studies that you identified
8 in your next step?

9 A. No.

10 Q. You'd have to conduct these tests; right?

11 A. Correct.

12 Q. Is there anything in the literature that would assist
13 one skilled in the art to make this prediction that you're
14 aware of?

15 A. Not with atomoxetine hydrochloride, or its salts.

16 Q. All right. So now that you've refined the formula, so
17 what is the next step one of ordinary skill in the art would
18 have to conduct?

19 A. In my assessment, you'd have to take this to animal PK
20 studies and determine whether or not it would be safe to go
21 to humans. And we'd be very interested in trying to
22 determine the relationship of any blood level we achieved
23 with our dose.

24 Q. Now, you mentioned before you had -- I'm sorry, can
25 you repeat? So in order to confirm that it would be safe to

1 go into humans? Can you repeat that?

2 A. Yes. Our goal is to try to exercise this claim one,
3 and to do that, we have to do a human efficacy study. The
4 problem is, we don't know the dose, we don't know the
5 safety. So we -- and in my discussions with people from the
6 pharmaceuticals group at FDA, they suggest that we do -- have
7 to at least do dogs and probably rats, and they thought I
8 would have to do monkeys. And we've done dogs and rats and
9 mice, but we haven't done the monkeys yet.

10 Q. All right. Well, let's just go back, and let's focus
11 a little bit on the animal PK studies.

12 What animal would you use in testing?

13 A. We'd start with rats because it's easy, you can do it
14 fast, and it's a reasonable in vitro model.

15 Q. And approximately how long would it take to conduct
16 these studies?

17 A. You'd probably have to do at least two or three --
18 you'd probably do multiple stages, because what we don't
19 know now would be the effect of a single-dose study,
20 multiple-dose studies, or injection site location. So we
21 would probably repeat these, and these would be -- we'd
22 probably work -- and my plan as I recall was about a year,
23 nine months to a year.

24 Q. Just to do the animal PK studies?

25 A. Right. Right.

1 Q. Now, you used the word "PK." What does PK stand for?

2 A. Pharmacokinetic.

3 Q. And what is it that you're --

4 A. Well, we try to determine the parameters of excretion,
5 absorption, and dissolution from or at least partitioning
6 from our dosage form into the bloodstream so we have an idea
7 of relationship of dose versus blood level that we would
8 achieve.

9 Q. Are you also getting a relation with respect to
10 release?

11 A. Yes.

12 Q. Now, how would one measure -- I mean, what kind of
13 analysis would one have to carry out to determine the
14 release? I mean --

15 A. Typically, we would do it -- we would do a blood level
16 study first with an injectable solution, so we would get the
17 purer, let's call them, pharmacokinetic parameters, and then
18 we would start injecting our dosage form at probably at
19 least two doses.

20 Q. Okay. As to now when you say -- I just want to get
21 into the how. So how? You inject rats, you extract blood?

22 A. Right.

23 Q. What does the analysis entail?

24 A. We analyze it with an LCMS device, an analytical
25 technique.

1 Q. That's going to require a development standard, is it
2 not?

3 A. You have to do standards. You have to do -- you have
4 to develop an analytical method. That's -- and then in this
5 case, it's probably a two- to four-week to three-month job.

6 Q. To develop the analytical test --

7 A. For the plasma, depending on the level -- level that
8 you're studying. If it's very low levels, it takes longer.

9 Q. I just want to be clear. You mentioned as far as
10 carrying out the analytics, you have to develop the
11 analytical test methodology; correct?

12 A. Correct.

13 Q. And that would take some time?

14 A. Yes.

15 Q. And how long do you think that would take?

16 A. One to three months.

17 Q. Okay. Now, you also mentioned irritation. So why is
18 that a test that's carried out?

19 A. If it's irritating at the injection site, you may be
20 dead in the water quick.

21 Q. And so how is that test carried out?

22 A. We will biopsy the site. We'll look at the surface
23 and see whether or not it's puffy, red, mounded, and we'll
24 biopsy it and prepare slides, go to a pathologist, and he'll
25 look at them.

1 Q. Now, at this point, if I -- again, you have a circular
2 arrow next to the animal PK studies and irritation stage.

3 I'm referring to slide 23. What does this indicate?

4 A. Iterative steps.

5 Q. And any idea, in your own experience, how many cycles
6 that may go through or could go through?

7 A. It could be many. We've gone through many with
8 buphenophrine where we have gone through many iterations and
9 variety of concentrations. We've gone through a variety of
10 dose levels. It's --

11 Q. Now, what comes next? Okay? After you -- you've made
12 a refined formulation, now, you've carried out a series of
13 animal PK studies and irritation studies. So what's the
14 next step for one of ordinary skill in the art?

15 A. We would want to do human PK studies to get a
16 relationship of the dose we would want to try with people.

17 Q. Why would you have to carry out human PK studies?

18 A. Because we don't know the dose.

19 Q. Well, what information, what data would you need to
20 extract from these studies?

21 A. We would try to get a relationship between the blood
22 level and the injection amount.

23 Q. Particle size of the compound, would that also be --

24 A. It would -- we would hope we would have refined it
25 sufficiently by this time we don't have to keep repeating

1 it, but that would -- for an insoluble salt, that would be
2 an issue.

3 Q. Okay. Now, these human PK studies, these are not
4 individuals that have ADHD; right?

5 A. No, these are -- this is --

6 Q. Healthy volunteers?

7 A. Yes.

8 Q. How many patients would be necessary to carry out
9 these studies, to sufficiently carry out these studies?

10 A. You'd probably do a pilot study of four to six people,
11 and then to get really good results, you'd probably need at
12 least a dozen.

13 Q. So you have to go from four to six people, get some
14 results --

15 A. Well, you'd work out your technique and everything.
16 You'd want to do a pilot study with this. It's a new dosage
17 form, it's not -- not routine.

18 Q. Right. So in fact, let me ask you this, then. With
19 respect to the animal PK studies and the irritation studies,
20 would you consider those tests to be routine?

21 A. No.

22 Q. Why not?

23 A. They're very, very difficult and sophisticated in
24 interpretation.

25 Q. What about it makes it difficult?

1 A. Interpretation of the data.

2 Q. Okay. So what is it about the data that one skilled
3 in the art would find challenging in interpreting?

4 A. To try to relate the release of the drug back to the
5 blood level. There's so many things that happen, it just
6 doesn't seem to be real simple. It's not always
7 straightforward.

8 Q. Can you give us an example of some of the things that
9 could happen?

10 A. When you inject these, you may have injected not
11 consistently in the right site. In other words, you -- the
12 technician may have rubbed the site. So many things happen
13 that -- it makes a difference.

14 Q. All right. Now, again, with respect to these studies
15 on slide 23, and I'm referring to the purple diamonds, okay,
16 up top, would you consider these tests individually as
17 routine?

18 A. Syringeability probably would be. Sterility -- we
19 would -- no. Injection site, no. Generally, they're not.

20 Q. Okay, but you said syringeability would --

21 A. Yes, we could train somebody to do that fairly simply.

22 Q. But your opinion is not the same with respect to the
23 other tests identified in the blue diamonds -- I'm sorry,
24 purple diamonds.

25 A. In my experience, that is not the case.

1 Q. And we're referring to one -- and again, when you're
2 giving -- your opinion is with respect to one of ordinary
3 skill in the art; correct?

4 A. Correct.

5 Q. So now you've carried out the human PK studies.

6 Did I ask how long would that take to carry out
7 the human PK studies?

8 A. I think you could probably do that in less than six
9 months.

10 Q. Less than six months. Approximately, can you give me
11 an approximation? More than three, four, five?

12 A. Well, you're not going to do it in less than three
13 months. You can maybe complete it in six.

14 Q. Now, obviously, you're a formulator.

15 A. Right.

16 Q. Who would carry out the human PK studies?

17 A. We'd go to a biopharmaceutics lab. We have a fellow
18 on campus who has done literally hundreds of tests like
19 this.

20 Q. Okay. So once those tests are carried out, and --
21 well, let me ask you this. Before you even get into human
22 efficacy studies, and we're going to talk about that in a
23 second, approximately how much would this cost to go from --
24 hold on -- to go from selecting the form of atomoxetine to
25 complete the human PK studies on slide 23, about how much

1 would that cost? Approximately.

2 A. It's millions of dollars. Alchemy spent I believe
3 tens of millions of dollars.

4 Q. This is how -- I'm now asking about the cost as you
5 would see it as of 1995, January 1995. Is that about --
6 would that be millions of dollars?

7 A. Well, roughly. It's just that -- it's my
8 understanding they kept repeating the human PK study because
9 it was very difficult to get it consistent and reproducible.

10 Q. So let me just ask you, so in your view, based on your
11 40 years of experience, okay, how much do you think it would
12 cost around as of 1995 to conduct all the tests from the
13 selection of the atomoxetine form to complete human PK
14 studies?

15 MR. BAJEFSKY: Objection, Your Honor. There's
16 nothing about cost in his expert report.

17 THE COURT: Well, I have a little, other
18 difficulty.

19 First of all, do you feel comfortable making a
20 guesstimate as to what it would cost back in 1995?

21 THE WITNESS: It's difficult.

22 THE COURT: Okay. Even if it's difficult, would
23 you feel comfortable, do you think you can make in any kind
24 of way an accurate assessment?

25 THE WITNESS: It's not -- it's not less than a

1 million, and it's -- from our scheme here, which is rather
2 simple, it's I'm sure less than 10. So two to five.

3 THE COURT: Well, now I've heard not less than a
4 million, two to five, and 10.

5 THE WITNESS: I'm trying to narrow it.

6 THE COURT: I know. Because it seems to me that
7 this verges on the impossible to try to make a legitimate
8 estimate of this.

9 So whether it's relevant or not relevant, I'm
10 having trouble with giving it much credibility.

11 MR. PARKER: Well, let me just see if I can --

12 Q. Dr. Johnson, in your experiences, as part of your
13 responsibilities at Schering-Plough, did you have to advise
14 the company as to --

15 THE COURT: One of my problems here is trying to
16 put this into 1995 dollars.

17 MR. PARKER: Right.

18 THE COURT: And you know, even though -- I don't
19 know how we do this.

20 Why don't we go on to another subject?

21 MR. PARKER: Okay.

22 THE COURT: In the couple of minutes that we have
23 left.

24 BY MR. PARKER:

25 Q. Okay. Now, Dr. Johnson, now that we've gone through

1 human PK studies, what is the next step one with ordinary
2 skill in the art would have to undertake?

3 A. We would have to do a human efficacy study.

4 Q. And why is that?

5 A. Because in the exercise of the practice of the '590
6 invention, you have to show human efficacy.

7 Q. What is it about the claim that says you have to show
8 or have human efficacy?

9 A. It's for treating ADHD and administering atomoxetine.

10 Q. Does the claim recite the word, the phrase "effective
11 amount"?

12 A. Yes.

13 Q. Does that have any -- does that also relate to whether
14 or not you would have to conduct human efficacy studies?

15 A. I think so.

16 Q. So, again, now, is it your goal in -- with respect to
17 this schematic, this -- in terms of developing a depot
18 injection, is it your -- are you describing the process in
19 which you would actually end up with a product that would be
20 approved by the FDA for commercial marketing?

21 A. No. What we're trying to get here is a dosage form
22 which would treat a small number of people for four to six
23 weeks to determine whether or not this dosage form would
24 have efficacy.

25 Q. And how long do you think it would take, based on your

1 experience, how long do you think it would take to have
2 these studies carried out, human efficacy studies?

3 A. Probably six months or more.

4 Q. Now, in human PK studies, you also have an indication,
5 you have a rounded circle. What is that related to, mean?

6 A. That means that you might have to repeat these studies
7 with a modified dosage form.

8 Q. In your experience, when developing a depot injection,
9 what are some of the challenges that one would encounter?

10 A. Starting from the beginning or the end? I mean, in
11 the first place, you really have to find something that's
12 going to release the drug in sort of the manner and rate
13 that you think would be acceptable for the period of time
14 you've selected, so you try to decide, is this a seven-day
15 dosage form, is it a one-month dosage form. That goes to
16 determining which technique am I going to try to determine
17 is useful for making one of these dosage forms.

18 Q. What about the term dose dumping?

19 A. That's what you've got to be very careful with. Any
20 sustained-release dosage form, even if it's just a simple
21 oral dosage form, if the dose dumps, that can cause toxicity
22 problems. Now, with the sustained release, if you have a
23 one-month dose that dumps for some reason or other, it could
24 kill someone. So it's not -- not reasonable to take dosage
25 forms that aren't really thoroughly tested into a clinic and

1 determine whether or not it's going to -- going to work and
2 show efficacy.

3 Q. Now, is dose dumping a challenge that one would have
4 to deal with in development?

5 A. That's one of the big challenges.

6 Q. Now, based on your consideration of the Wands factors,
7 have you formed an opinion as to whether as of January 11th,
8 1995, undue experimentation would have been required by a
9 person of ordinary skill in the art to prepare a depot
10 injection in an effective amount of atomoxetine to treat
11 ADHD?

12 A. I would think it would cause undue experimentation.

13 Q. Now, you know that --

14 MR. PARKER: Well, Your Honor, I can -- just a
15 couple minutes or, do you want to go to exactly three?

16 THE COURT: I don't want to go later.

17 (Laughter)

18 BY MR. PARKER:

19 Q. Dr. Johnson, you are aware that Plaintiff has retained
20 a formulator expert, Dr. McGinity?

21 A. Yes.

22 Q. And did you read his deposition testimony?

23 A. Yes.

24 Q. Okay. Well, let me ask you this question. Could
25 someone simply take sesame seed oil, take atomoxetine

1 hydrochloride, put it all together and just use that as a
2 depot injection?

3 Let me go one step further. Let's assume
4 hypothetically you had a tablet, and you knew the tablet had
5 60 milligrams of atomoxetine hydrochloride, and you knew
6 that tablet was effective for treating ADHD. Could you
7 simply grind that tablet up put it in sesame oil and call
8 that a depot injection?

9 A. I'd be afraid to do that.

10 Q. Would you put that in your child?

11 A. No. Do you think a pharmacist -- do you believe that
12 a physician would actually ask a pharmacist to compound a
13 depot injection for treatment of ADHD in a child or an
14 adult?

15 A. I don't believe he would.

16 Q. Are you familiar with the treatises, Remington and
17 Ancill (ph) and --

18 A. Lockman (ph).

19 Q. Oh, Lockman. Are you familiar with those treatises?

20 A. Yes.

21 Q. Could one of ordinary skill simply look to these
22 treatises and be able to find a nice recipe and be able to
23 develop a depot injection of atomoxetine to treat ADHD?

24 A. You could use these for starting points, but they
25 wouldn't really provide very much help.

1 Q. And would your opinion change one way or the other as
2 to the level of undue experimentation that would be
3 necessary?

4 A. No. In fact, we did use Lockman, I believe, in that.
5 I believe we have used these in the past as references and
6 starting points.

7 MR. PARKER: This would be a good point to stop,
8 Your Honor.

9 THE COURT: All right.

10 All right. Well, we will resume, then, on Monday.

11 Now, I have a problem on Monday morning. What are
12 we doing? A sentence?

13 We're going to start at 10 o'clock Monday morning.

14 Believe it or not, I have lots of other things
15 going on.

16 (Laughter)

17 THE COURT: Next week, perhaps, there are a couple
18 of days we might go a little later than four to try to make
19 up some of the time. So why don't we see where we're going?

20 And other than that, we'll see everybody here at
21 10 o'clock on Monday morning.

22 Enjoy your weekend.

23 (Matter adjourned until Monday, May 24, 2010,
24 commencing at 10 a.m.)

25

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